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OVERVIEW

We are an innovation- and R&D-driven biotech company established in 2012, dedicated to the development, manufacturing and commercialization of novel drugs for the treatment of viral infections, oncological and cardio-cerebrovascular diseases. We have built a comprehensive drug portfolio, primarily consisting of seven drug candidates, including three Core Products. In particular, centered on azvudine (brand name: 捷倍安®), our Core Product, a conditionally approved drug for the treatment of HIV infection and COVID-19 in China, we are developing a monotherapy for the treatment of multiple myeloma, lymphoma and acute leukemia, a monotherapy for the treatment of immunological non-responders (INRs) in HIV-infected patients, as well as four combination therapies including azvudine + anti-PD-1 for the treatment of liver cancer and colorectal cancer, azvudine + dosimertinib for the treatment of non-small cell lung cancer (NSCLC), azvudine/CL-197 for the treatment of HIV and azvudine + CTX for the treatment of lymphoma. Our other six drug candidates include (i) CL-197, our Core Product, for the long-acting treatment of HIV infection; (ii) dosimertinib, our Core Product, for the treatment of NSCLC; (iii) ZSSW-136 for the treatment of malignant tumor, (iv) MTB-1806 for the treatment of acute ischemic stroke (AIS); (v) ZS-2004 for the treatment of solid tumors; and (vi) ZS-1004 for the treatment of solid tumors.

We have an in-house R&D management team composed of senior experts in the field of international drug research and development. Dr. Du Jinfa (杜錦發), the chairman of our Board, executive Director, chief executive officer, chief scientific officer of our Company, recognized as “State Specially Recruited Experts (國家特聘專家)” by the PRC government, is one of the inventors of sofosbuvir, drug for treating hepatitis C which won the Prix Galien Award, and one of the inventors of azvudine (for the treatment of COVID-19), CL-197 and dosimertinib, our Core Products. *Cell* has commented that sofosbuvir is one of the most significant public health accomplishments of our generation. Our senior management personnel, such as Dr. Dang Qun, Dr. Guo Chang Yue and Dr. Li Pan, all have served in internationally-renowned biomedical companies with an average of nearly 30 years of extensive experience in the fields of innovative drug research and development, translational medicine, and clinical trial management, which has laid a solid foundation for our continuous innovation and global competitiveness. Leveraging our extensive experience in drug research and development, we have established comprehensive research and development platforms, including a highly selective novel nucleoside broad-spectrum anti-tumor drug R&D platform, a TOPO1 inhibitor and XDC drug R&D platform, a drug target discovery and validation platform, and an innovative drug design and optimization platform. These platforms cover the entire drug development process, from early target screening to preclinical research, to clinical trials and subsequent optimization, providing strong technical support and systematic safeguards to accelerate the discovery and development of innovative drugs.

In terms of the treatment of viral infections, our Core Product, azvudine, a Class 1.1 innovative drug, was conditionally approved by the NMPA for the treatment of HIV infection and COVID-19 in July 2021 and July 2022, respectively. Azvudine was the first NMPA-approved oral antiviral treatment for COVID-19 developed by a Chinese company, demonstrating antiviral activity in preclinical and/or clinical studies. It not only inhibits viral replications but also enhances immune function, achieving a dual effect of “addressing both symptoms and root causes.” With cumulative sales exceeding 10 million bottles, the safety profile and efficacy of azvudine have been validated by real-world data and supported by 177 research papers published by independent third parties. With its unique dual target mechanism of action, azvudine has become the world’s first HIV infection treatment option for the dual-targeted inhibition of nucleoside reverse transcriptase and the Vif. In addition, in our Phase II clinical trial, azvudine demonstrated antiviral activity that was broadly comparable to that observed for another NRTI, lamivudine at a lower dose level. Furthermore, we are also developing CL-197, our Core Product, a novel oral HIV drug candidate demonstrating a long half-life of over 168 hours in animal pharmacokinetic studies after oral administration, which supports once-weekly dosing for CL-197. Compared to once-a-day dosing, once-a-week dosing is a more convenient drug regimen and may also improve medication compliance and thus improve clinical outcomes. Leveraging its outstanding efficacy in viral infection treatment and the long-acting mechanism, our azvudine/CL-197 combination tablet shows the potential to become an all-oral, long-acting and weekly administered treatment for HIV. We have also been leveraging our independent R&D capabilities to expand the applications of azvudine in new indications and combination treatment in cancer treatment.

In the field of oncology, we are exploring the potential applications of our Core Product, azvudine, a nucleoside-based drug candidate. Azvudine is under investigation in oncology-related research settings based on its proposed mechanisms of action. It can exert its anti-tumor effects by inhibiting DNA synthesis in tumor cells and enhancing immunity through immunomodulation. We are also developing dosimertinib, our Core Product, a clinical-stage, Class 1 innovative third-generation EGFR-TKI drug candidate. The Phase I trial results showed that dosimertinib has a

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similar efficacy to osimertinib, a widely-used third generation EGFR-TKI. We are continuously expanding the applications of azvudine into new indications and combination treatment, including (i) azvudine + anti-PD-1 combination therapy for the treatment of liver and colorectal cancer, where 100% tumor remission was observed in animal studies; (ii) azvudine + dosimertinib combination therapy for the treatment of NSCLC, demonstrating a 92.82% tumor inhibition rate in animal models; and (iii) azvudine monotherapy and azvudine + CTX combination therapy for blood cancer, where single-agent treatment showed a significant inhibitory effect on blood tumors and combination treatment achieved 100% tumor remission in animal studies.

In addition, our TOPO1 inhibitor platform features an innovative non-camptothecin parent nucleus structure and demonstrates broad-spectrum anti-tumor activity. ZSSW-136, being the first small-molecule PCC compound discovered under this platform, has unique advantages in overcoming the resistance to commonly used anti-tumor drugs. Preclinical studies have shown that its inhibitory effect on irinotecan-resistant human cancer organoids is 400 times greater than that of irinotecan. Besides, recent studies in colorectal cancer cells indicate that ZSSW-136 could have potential clinical benefits in extending PFS compared to irinotecan, if used in the first-line irinotecan-based therapies. It also has the potential for broad application in various XDC (e.g. ADC, PDC, SMDC) drug conjugate projects as a novel payload, offering promising solutions to the drug resistance in a wide range of tumors.

The following table summarizes our product portfolio and the status of each drug or drug candidate as of the Latest Practicable Date:

Drug/Drug Candidate	Mono/combo therapy	Indication	Target	Modality	Route of Administration	Preclinical	Phase I	Phase II	Phase III/ Pivotal	Competent authority	Commercialization Rights	Next Milestone
Azvudine*	Monotherapy	HIV infection	RT-c/Vif	Small molecule	Oral	NMPA conditional approval ⁽¹⁾				NMPA	Global ⁽³⁾	Obtain regular approval in the first half of 2027
		COVID-19	RdRp		Oral	NMPA conditional approval ⁽²⁾				NMPA	Global ⁽³⁾	Obtain regular approval in the first half of 2026
	Monotherapy	Multiple myeloma ⁽⁴⁾	DNA		Oral					NMPA	Global	Initiate Phase IIa clinical trial in 2026
		Lymphoma ⁽⁴⁾								NMPA	Global	
		Acute leukemia ⁽⁴⁾								NMPA	Global	
	Monotherapy	INRs in HIV-infected patients ⁽⁴⁾	RT-c/Vif		Oral					NMPA	Global	Application for pivotal trial in the second half of 2026
	Azvudine + anti-PD-1 combination therapy	Liver cancer ⁽⁴⁾	DNA-MDSC/ PD-1		Oral (anti-PD-1 agent by injection)					FDA		IND application for Phase I trial in 2027
		Colorectal cancer ⁽⁴⁾								NMPA	Global	Commence Phase I trial in the second half of 2026
	Azvudine + dosimertinib combination therapy	NSCLC ⁽⁴⁾	DNA-MDSC/ EGFR		Oral					NMPA	Global	Complete stage 1 of Phase I trial in the second half of 2026, complete stage 2 of Phase II trial in 2028
	Azvudine + CTX combination therapy	Lymphoma ⁽⁴⁾	DNA/ chemotherapy		Oral (CTX agent by injection)					NMPA	Global	IND application for Phase I trial in the second half of 2026
	All-oral long-acting composite tablet (Azvudine/CL-197) combination therapy	HIV infection	RT-c/Vif/RT-p		Oral					NMPA	Global	IND application in the second half of 2026
	CL-197*	Monotherapy	HIV infection		RT-p	Small molecule	Oral					NMPA
Dosimertinib*	Monotherapy	NSCLC	EGFR	Small molecule	Oral					NMPA	Global	Complete Phase II trial in the second half of 2026
ZSSW-136	Monotherapy	Malignant tumor, Irinotecan-resistant tumor	TOPO1	Small molecule	IV					NMPA	Global	IND application for Phase I trial in the second half of 2026
MTB-1806	Monotherapy	AIS	15-LOX-2	Small molecule	Oral					NMPA	Global	IND application for Phase I trial in the second half of 2026
ZS-2004	Monotherapy	Solid tumors	GRPR	RDC	IV					NMPA	Global	IND application for Phase I trial in 2027
ZS-1004	Monotherapy	Solid tumors	PSMA	ADC	IV					NMPA	Global	IND application for Phase I trial in 2027

 : China, regulated by NMPA
 : US, regulated by FDA
 : Denotes anti-tumor drug candidates

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* Core Product

15-LOX-2: 15 lipoxygenase subtype 2
 AIS: acute ischemic stroke
 CNS: central nervous system
 CTX: cyclophosphamide
 EGFR: epidermal growth factor receptor

MDSC: myeloid-derived suppressor cells
 NSCLC: non-small cell lung cancer

PD-1: programmed cell death protein 1
 RdRp: RNA-dependent RNA polymerase
 RT: reverse transcriptase
 TOPO1: topoisomerase I
 Vif: virion infectivity factor
 GRPR: gastrin-releasing peptide receptor
 PSMA: prostate-specific membrane antigen
 RDC: radionuclide drug conjugate
 ADC: antibody-drug conjugate

Notes:

- (1) We obtained a conditional approval of azvudine for the treatment of HIV infection from the NMPA in July 2021. Pursuant to the approval, we could commence commercial sales of azvudine for the HIV indication in China and shall conduct a Phase III clinical trial, submit safety reports periodically and submit a Phase III clinical trial report within five years from the date of approval. We completed the last visit of the last patient for the Phase III clinical trial in June 2025, and completed the CSR in April 2026. We have submitted an application for a conversion from conditional approval to a regular approval in April 2026, and expect to obtain the regular approval in the first half of 2027. See “—Our Product Portfolio—Azvudine—Our Core Product—HIV Infection.”
- (2) We obtained a conditional approval from the NMPA for indication expansion of azvudine to the treatment of common COVID-19 in adults in July 2022. Pursuant to the approval, we could commence commercial sales of azvudine for the COVID-19 indication in China and shall (i) conduct pharmacodynamic studies of azvudine against mutant variants of the SARS-CoV-2 virus; (ii) actively progress ongoing clinical trials of azvudine and submit trial reports upon completion; (iii) continue to collect efficacy and safety clinical data post-approval; and (iv) submit the required materials within three years of approval. We have completed all of the required R&D work and submitted an application for a conversion of the conditional approval to a regular approval in July 2025, and we expect to obtain the regular approval in the first half of 2026.
- (3) In April 2020, Henan Genuine entered into a framework agreement with Beijing Union to authorize Beijing Union to fully carry out registrations, clinical applications and market collaboration matters of azvudine in Russia and Ukraine. Beijing Union will be the MAH and act as the manufacturer of azvudine in Russia and Ukraine after it obtains marketing approval in these countries. As of the Latest Practicable Date, Beijing Union had completed phase III clinical trial for azvudine as a COVID-19 treatment and was approved for marketing by the Russian MoH in February 2023, but we had not generated any income under this collaboration arrangement. In June 2020, Henan Genuine entered into a tripartite framework agreement with Beijing Union and an Independent Third Party agent to authorize Beijing Union to cooperate with the agent to carry out registration applications, clinical trials and market collaboration matters of azvudine for treating COVID-19 in Brazil and the Union of South American Nations (UNASUR). In November 2021, Henan Genuine entered into a supplemental tripartite collaboration agreement, as further supplemented thereafter, with Beijing Union and an affiliate of the agent, who is also an Independent Third Party. Pursuant to these agreements, after azvudine for the COVID-19 indication is approved for marketing in Brazil, Beijing Union shall act as the manufacturer for such product in Brazil and the affiliate shall be the MAH of azvudine in Brazil and have exclusive marketing rights in Brazil and the other regions of South America. See “—Our Technology Transfer Arrangements and Collaborations” for details.
- (4) We obtained an IND approval from the NMPA for the clinical trials of azvudine in patients with advanced solid tumors, and initiated a Phase I clinical trial in January 2025, the results of which are expected to be used to support the design of future combination studies and full development of solid tumor indications. Such data will also be used to support the development for the treatment of blood cancer as the safety, tolerability and PK data are inherently applicable for later-phase clinical trials of other cancers. Such Phase I trial and CSR were completed in June 2025, based on which (i) we submitted the IND application for the Phase II clinical trial of azvudine monotherapy for the treatment of blood cancers, received acceptance notification in September 2025 and obtained the IND approval in December 2025, (ii) we submitted the IND application of azvudine + dosimertinib for the treatment of NSCLC in July 2025, and received the IND approval in September 2025, and initiated a Phase I/IIa trial in November 2025, and (iii) we submitted an IND application of azvudine + anti-PD-1 for the treatment of liver cancer and colorectal cancer in December 2025, and obtained the IND approval in February 2026. We expect to submit an IND application for azvudine + CTX for the treatment of lymphoma in the second half of 2026 after collecting more pharmacology and safety data from the azvudine monotherapy for the treatment of blood cancers. In addition, leveraging the clinical results generated from the Phase I and Phase II clinical trials and the relevant IIT study, we plan to initiate a Phase II/III pivotal study for the treatment of INRs in HIV-infected patients in China in the second half of 2026, on the basis of the conditional approval of azvudine granted by the NMPA. Besides, we plan to submit an IND application for Phase I clinical trial of the same therapy in the US in 2027.
- (5) As denoted by the dotted line, we have obtained the conditional approval for azvudine for the treatment of HIV infection from the NMPA in July 2021, and therefore we expect to skip the Phase I/II stage and directly initiate a Phase III/pivotal trial, subject to further communication with the NMPA.

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COMPETITIVE STRENGTHS

A competitive pipeline of innovative and long-acting drugs for the treatment of HIV infection providing more convenient and effective treatment options for HIV patients worldwide

According to Frost & Sullivan, approximately 43.7 million people globally were living with HIV in 2024. The global HIV drug market increased from US\$37.0 billion in 2019 to US\$46.7 billion in 2024, and is expected to further increase to US\$61.0 billion in 2030, representing a CAGR of 4.5% from 2024 to 2030.

Antiretroviral therapy (ART) is the current standard of care for the treatment of HIV infection and requires lifelong treatment. However, missed doses may lead to drug resistance and disease progression, and prolonged drug exposure may result in drug-resistant HIV strains that could render the existing antiretroviral drugs partially or fully inactive. Accordingly, improving compliance and reducing drug resistance risks are two focuses of HIV therapy development. Leveraging our R&D team's track record in developing antiviral drugs, we have built a pipeline of HIV drug, drug candidate and combination treatment at various stages of research and development. We aim to provide HIV patients around the world with more convenient and effective drug choices and treatment regime.

Azvodine: a nucleoside-based orally-administered reverse transcriptase (RT) and accessory protein Vif dual-target inhibitor treating HIV infection

Azvodine, our Core Product, was conditionally approved by the NMPA in July 2021 as a national Class 1 innovative drug for treating HIV-1 infected adults with high viral load. Azvodine is a pyrimidine nucleoside antiviral drug with a mechanism of action involving reverse transcriptase (RT) inhibition. Azvodine has demonstrated good efficacy and is potentially suitable for oral administration with extended dosing intervals in combination therapy settings. In addition, azvodine has been listed as one of the National Science and Technology Major Projects (Major New Drug Innovation) in China. Azvodine was included in the 2021 and 2024 China AIDS Treatment Guidelines after it was approved by the NMPA.

Based on its proposed dual-target mechanism of action, azvodine is being explored in HIV-related research. Ongoing studies are assessing its pharmacological characteristics and potential applications. The commercial prospects of azvodine remain subject to further clinical development, regulatory approval and market conditions.

CL-197: an orally administered drug candidate being evaluated for extended dosing intervals

We are developing CL-197, our Core Product, an orally administered purine nucleoside antiviral drug candidate. Pharmacokinetic studies in animal models via oral gavage administration have shown that CL-197 has a half-life of approximately 168 hours in PBMC.

The current R&D of HIV drugs focuses on improving drug safety, resistance and treatment simplification (such as a single-tablet and/or less frequent dosing regimen) for improved compliance. We completed the Phase I clinical trial in March 2025, in which CL-197 demonstrated safety, tolerability and PK characteristics; and commenced the Phase IIa trial in November 2025, and expect to complete the Phase IIa trial and initiate Phase IIb trial in 2026.

Azvodine/CL-197 composite tablet: potentially all-oral long-acting HIV treatment regimen

We are developing a composite tablet comprising azvodine and CL-197. Combination antiretroviral therapy (cART) is a treatment approach that has been widely adopted in clinical practice for HIV infection which can suppress viral replication and reduce the risk of drug resistance associated with monotherapy. Among the drug classes used in cART regimens, nucleoside reverse transcriptase inhibitors (NRTIs) are commonly included as part of the treatment backbone which, according to Frost & Sullivan, have been used in HIV treatment for an extended period.

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A wide range of potential options exist for azvudine, our NMPA-approved novel NRTI HIV drug, to combine with other antiretroviral drugs to form effective cART regimens for the treatment of HIV infection. For example, both azvudine and our drug candidate CL-197 have demonstrated long-acting features in preclinical trials, the combination of which has the potential to form the all-oral long-acting and weekly administered composite tablet globally, which may help reduce the risk of drug resistance.

An oncology pipeline comprising multiple investigational drug candidates targeting areas with significant unmet medical needs

Our pipeline included a number of anti-tumor products in various stages of development, covering the treatment of various types of tumors.

Azvudine: a nucleoside-based drug candidate under evaluation for oncology-related indications

Azvudine is a nucleoside-based compound under investigation with two proposed mechanisms of action relevant to oncology research, *i.e.*, it can inhibit the DNA synthesis of tumor cells and improve immunity through immune regulation to exert further anti-tumor effects. We obtained an IND approval from the NMPA for the clinical trials of azvudine in patients with advanced solid tumors, and initiated a Phase I clinical trial in January 2025, the results of which are expected to support future combination studies and full development of solid tumor indications, and to provide safety, tolerability and PK data for the the development of blood cancer indications.

Combination therapy has been increasingly explored in cancer treatment. We have adopted a scientific guiding strategy that is centered on our Core Product, azvudine, and are developing an Azvudine⁺ Platform, aiming to further explore the clinical and commercial potential of azvudine. Consequently, we are actively engaged in research and development to explore the potential of combining azvudine with tumor immunotherapy drugs (*e.g.*, agents targeting PD-1), targeted therapy drugs (*e.g.*, dosimertinib), and chemotherapy drugs (*e.g.*, CTX). As of the Latest Practicable Date, we had initiated the R&D of the following combination therapies involving azvudine:

- *Azvudine + Anti-PD-1*: The combination therapy could reactivate T cells via PD-1 pathway suppression, resulting in anti-tumor effects. We have conducted preclinical studies and investigator-initiated clinical study of azvudine + Anti-PD-1 in liver cancer and colorectal cancer. We are initiating further clinical trials in leading hospitals in Beijing and Shanghai to facilitate the development of solid tumor indications of azvudine to address unmet clinical needs in this field. We submitted IND applications for the two indications to the NMPA in December 2025, and obtained the IND approvals in February 2026.
- *Azvudine + dosimertinib*: Our preclinical *in vivo* studies have evaluated the activity of azvudine in NSCLC models harboring the EGFR T790M mutation. The results indicate that azvudine demonstrated tumor growth inhibition in these preclinical models. We have completed the preclinical studies of azvudine + dosimertinib in NSCLC and received an IND approval from the NMPA in September 2025 based on the clinical data from the Phase I clinical trial of azvudine in patients with advanced solid tumors and the clinical data from the Phase I clinical trial of dosimertinib.
- *Azvudine + CTX*: The azvudine + CTX combination therapy is being explored based on the respective mechanisms of action of azvudine and CTX, an alkylating agent that is known to induce DNA cross-linking and interfere with DNA synthesis. We have completed the preclinical studies of azvudine + CTX in lymphoma and plan to submit an IND application to the NMPA in the second half of 2026 after collecting more pharmacology and safety data from the azvudine monotherapy for the treatment of blood cancers as suggested by the CDE in a pre-IND communication in August 2025.

In addition, our *in vitro* and *in vivo* studies have demonstrated the effectiveness of azvudine monotherapy for hematological tumors. The results suggest that azvudine demonstrated antitumor activity in these preclinical models. *In vitro* studies have shown that azvudine inhibits cell proliferation. Our *in vivo* studies also showed that azvudine (2 mg/kg) achieved 100% tumor remission in the Jeko-1 model and 100% tumor remission in the Jurkat model. We obtained an IND approval from the NMPA for the clinical trials of azvudine in patients with advanced solid tumors, and initiated a Phase I clinical trial in January 2025. Such Phase I trial and CSR were completed in June 2025, based on which we submitted the IND application for the Phase II clinical trial of azvudine monotherapy for the treatment of blood cancers, received acceptance notification in September 2025 and obtained the IND approval in December 2025.

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Based on preclinical studies and investigator-initiated trial (IIT) results, we are exploring the potential applications of various combination therapy and monotherapy programs in oncology. We aim to accelerate the R&D process of azvudine in the anti-tumor field and aspire to establish ourselves as a competitive biotech company in oncology.

Dosimertinib: third-generation new EGFR TKI drug candidate with potential safety characteristics observed

Dosimertinib, our Core Product, is a clinical-stage, Class 1 innovative third-generation EGFR-TKI drug candidate with a potentially favorable safety profile. Compared to osimertinib, a widely used third-generation EGFR-TKI, preclinical trial results showed that dosimertinib can reduce potential toxic metabolites by up to 80% with comparable efficacy, and thus is expected to have a better clinical safety profile. Preclinical pharmacokinetic studies have shown that dosimertinib has an advantage in the treatment of lung cancer and brain metastases. We are conducting a Phase I/Phase II clinical trial in China to investigate the safety and efficacy of dosimertinib. We had completed the Phase I dose escalation clinical trial in May 2025, and the amendment of the Phase II dose expansion clinical trial protocol was approved by the CDE in May 2025, with its first patient enrolled in June 2025. According to the Phase I trial results, no DLTs were observed in the dosimertinib 20 mg, 40 mg, 80 mg, 160 mg, 200 mg or the 240 mg dose group, overall safety profile was good, and we have also observed a good dose-related efficacy. We believe dosimertinib could become a competitive treatment option for EGFR mutation-positive NSCLC.

ZSSW-136

ZSSW-136 is a novel inhibitor of topoisomerase I (TOPO1) enzymes which participate in the overwinding or underwinding of DNA and are particularly vulnerable to TOPO1 inhibitors during their cleavage reaction. Over the past few decades, the most widely used TOPO1 inhibitor has been irinotecan, a camptothecin (CPT) derivative, which has become the backbone of various anti-tumor combination therapies. However, CPT-based drugs face the problems of primary and post-treatment drug resistance. Utilizing an AI-Computer Assisted Drug Design (CADD) method we have developed in-house, we successfully replaced one of the five rings for the core nucleus of CPT, which led to the discovery of a new generation of innovative TOPO1 inhibitors and a novel ADC payload platform with strong global IP protection positions.

We have discovered a PCC molecule, ZSSW-136, that exhibits broad-spectrum antitumor activity and can effectively inhibit dozens of cancer cells at nano-molar concentrations. We have discovered hundreds of novel molecules, from which we have selected several payload compound candidates with potential payload properties. More importantly, our payload molecules have a completely new parent nucleus structure, thus potentially addressing the drug resistance issue of commonly used payloads. Since the new generation of payloads can overcome drug resistance, we have commenced external collaboration work to promote the application of our new payload technology platform to various XDC (ADC, PDC, SMDC, etc.) drug conjugate projects, resulting in a wide range of new drugs that will benefit our patients and simultaneously create substantial commercial values via licensing fees. We presented our findings at numerous conferences (such as 2025 AACR, EACR and ESMO-TAT, etc.), highlighting our novel payload platform and its capabilities to address the resistance problems for current TOPO1-based ADC drugs. Multiple discussions with leading ADC and antibody companies are ongoing to utilize our payload platform and jointly discover new ADC drugs to address the resistance issues.

Further studies are required to assess the clinical relevance of these preclinical findings. ZSSW-136 demonstrated potent inhibition of both wild type and mutant TOPO1 enzymes, thus when used as first-line therapy it is expected to double the OS for patients compared to the current TOPO1 inhibitors (such as irinotecan). Consequently, our development plans for ZSSW-136 were expanded to build a stronger case for its potential use as first-line therapies for certain solid tumors (e.g. colon cancers and SCLC), and we are also exploring the potential of using ZSSW-136 as an ADC payload; with these additional studies ongoing, we now plan to file IND in September 2026 and initiate clinical studies in early 2027.

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The first NMPA-approved oral antiviral treatment for COVID-19 developed by a Chinese company

Azvudine, our Core Product, is a nucleoside-based direct-acting antiviral (DAA) drug, conditionally approved by the NMPA for the treatment of common COVID-19 in adults. It is the first NMPA-approved oral DAA treatment for COVID-19 developed by a Chinese company. In April 2023, azvudine became the first domestically developed small-molecule oral medication for COVID-19 included in the NRDL. As of the Latest Practicable Date, azvudine had successfully completed the required online publication procedure for drugs covered by national medical insurance in an aggregate of 31 province-level divisions, covering an aggregate of over 50,000 medical institutions nationwide. This extensive coverage ensures the effective fulfillment of public medication needs. We have completed all of the required R&D work and submitted an application for a conversion of the conditional approval to a regular approval in July 2025, and we expect to obtain the regular approval in the first half of 2026.

As an RNA-dependent RNA polymerase (RdRp) inhibitor, azvudine can effectively suppress the replication of SARS-CoV-2, thereby terminating viral RNA chain elongation and virus replication. In the Phase III clinical trials in China and Russia, azvudine effectively reduced viral load in patients with a baseline viral load above a certain threshold and alleviated clinical symptoms for COVID-19 patients.

After azvudine was approved for marketing for the COVID-19 indication in China, it has demonstrated promising efficacy profile against the prevailing variants, including Omicron, according to studies based on post-marketing real-world data. Although the COVID-19 pandemic had gradually waned since the beginning of 2023, unpredictable seasonal surges may continue to occur, particularly during the winter season. We believe that azvudine remains an effective medication to treat COVID-19, and potential for maintaining relatively high efficacy toward new mutant strains. In addition, as an increasing global population has been experiencing long COVID symptoms following COVID-19 infection, we plan to explore the potential of azvudine for treating long COVID in overseas markets.

Integrated and comprehensive drug R&D platforms with proven capabilities in clinical development and experience in drug registration

We have established drug R&D platforms in Shanghai and Shenzhen and formed an experienced, professional and efficient in-house R&D team, driven by innovation and equipped with a global perspective. Leveraging our extensive experience in drug development, we have established integrated and comprehensive drug R&D platforms including (i) a highly selective novel nucleoside broad-spectrum anti-tumor drug R&D platform, (ii) a TOPO1 inhibitor and XDC drug R&D platform especially targeting tumors resistant to current ADCs, (iii) a drug target discovery and validation platform, and (iv) an innovative drug design and optimization platform, covering the entire drug development process. With our R&D platforms, we have already discovered the potential of azvudine to inhibit tumor and enhance anti-tumor effect of other treatments. We have also discovered ZSSW-136, a new generation of innovative small-molecule TOPO1 inhibitor and a novel ADC payload to address the drug resistance challenge induced by the traditional class of camptothecin drugs and commonly-used payloads through our TOPO1 inhibitor and XDC drug R&D platform. Our drug target discovery and validation platform enables us to quickly verify the efficacy after we design, modify and optimize the lead compounds through our drug design and optimization platform.

In addition, according to the “Notice of the Henan Provincial People’s Government on Establishing the First Batch of Henan Provincial Industrial Research Institutes and Naming the First Batch of Henan Provincial Pilot-Scale Bases (Yu Zheng Wen [2021] No. 152)” issued by the Henan Provincial Government in October 2021, we took the lead in establishing the Henan Provincial Modern Pharmaceutical Industry Research Institute. It was also proposed that the leading enterprise of the provincial industrial research institute should actively attract universities, research institutes and upstream and downstream enterprises to participate in the construction and operation of the industrial research institute, explore diversified component models with the deep integration of innovation chain and industrial chain as the link, and build the industrial research institute into an innovative consortium integrating R&D, pilot-scale testing, industrialization and engineering. As of the Latest Practicable Date, the establishment of Henan Modern Pharmaceutical Industry Research Institute had not materially impacted our business operation and financial position. We believe the integrated approach for academia, research, and application, among other areas, adopted by the institute and the guidance and policy support from relevant authorities could further enhance our R&D capability in the future.

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Our team, in collaboration with CROs and business partners, has successfully conducted clinical trials in China, Russia and Brazil, and has completed the registration of azvudine for two indications, namely, HIV and COVID-19, in China. We have also established and strictly enforced standard operating procedures for clinical trials to make sure our clinical trial operations are in compliance with the relevant GCP requirements of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the applicable regulatory requirements.

Strong Production, Commercialization Capabilities, and Various Sales Channels

Our production bases are equipped with industry-leading manufacturing facilities and technologies. Our annual production capacity is approximately 3 billion tablets, which not only meets our current market demand but also leaves plenty of room for future market expansion. In terms of quality control, our production base strictly follows the relevant regulations and standards of the NMPA and successfully passed the Good Manufacturing Practice (GMP) compliance inspection in May 2022. Our production and supply capabilities have laid a solid foundation for our long-term stable growth.

We have also developed a comprehensive commercialization strategy for azvudine and the investigational drug candidates, maximizing product value through an online and offline omni-channel promotion model combined with academic promotion. We have established a professional commercialization team covering multiple functions to ensure that products can be quickly promoted and achieve market penetration. We have established an offline dealer network across the country and signed contracts with 49 dealers to ensure product accessibility. In terms of online sales, we cooperate with mainstream e-commerce platforms to use digital marketing to promote the brand's influence.

In terms of product price management, azvudine was officially included in the NRDL in April 2023, and remained in the NRDL after our successful negotiation completed in November 2024. Azvudine has already covered an aggregate of more than 50,000 medical terminals in 31 provinces and cities across the country. In the future, after the approval of new indications, it can directly enter the hospital channel without repeating the hospital access procedure, further consolidating its market position.

Proven management team with good track record and support from professional investment institutions

Our management team is composed of experienced pioneers in drug R&D, with an average of around 30 years of experience in drug R&D and clinical trial management. Dr. Du Jinfa, the chairman of our Board, executive Director, chief executive officer, chief scientific officer of our Company, recognized as “State Specially Recruited Experts (國家特聘專家)” by the PRC government, is one of the inventors of sofosbuvir, drug for treating hepatitis C which won the Prix Galien Award, and one of the inventors of azvudine (for the treatment of COVID-19), CL-197 and dosimertinib, our Core Products. Our senior management personnel, such as Dr. Dang Qun, Dr. Guo Chang Yue and Dr. Li Pan, all have served in internationally-renowned biomedical companies and have an average of nearly 30 years of extensive experience in the fields of innovative drug research and development, translational medicine, and clinical trial management, which has laid a solid foundation for our continuous innovation and global competitiveness. See “Directors and Senior Management—Board of Directors—Members of Our Board” and “Directors and Senior Management—Board of Directors—Members of Our Senior Management” for details of relevant experience and areas of focus of our core R&D team members.

We have also received strong support from top-tier investors, including professional investors such as Efung Capital and Yingke PE that focus on investing in innovative pharmaceutical companies with great potential, and Shanghai Desano, a global supplier of anti-HIV active pharmaceutical ingredients.

OUR STRATEGIES

Our mission is to improve human health through genuine innovation. To accomplish this mission, we plan to pursue the following strategies.

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Quickly and efficiently advance the R&D, commercialization and post-approval regulatory processes of our Core Product, azvudine

Leveraging our strong clinical execution capabilities, we plan to quickly advance the development, commercialization and post-approval regulatory processes of azvudine for antiviral and anti-tumor therapies:

- HIV: we received a conditional approval from the NMPA of azvudine for treating HIV infection in July 2021 and have since begun the commercialization process. We also initiated the post-approval Phase III clinical trial in June 2022, completed the last visit of last patient in June 2025 and completed such trial in April 2026.
- Monotherapy for anti-tumor treatment: we obtained an IND approval from the NMPA for the clinical trials of azvudine in patients with advanced solid tumors, and Phase I clinical trial was initiated in January 2025 and completed in June 2025. Such data is also used to support the development for the treatment of blood cancer as the safety, tolerability and PK data are inherently applicable for later-phase clinical trials of other cancers.
- Combination therapy for anti-tumor treatment: we obtained an IND approval of azvudine + dosimertinib combination therapy for the treatment of NSCLC in September 2025 with the data collected from the Phase I clinical trial of azvudine in patients with advanced solid tumors completed in June 2025. We submitted an IND application to the NMPA for azvudine + anti-PD-1 combination therapy for the treatment of liver cancer and colorectal cancer in December 2025, and obtained the IND approval in February 2026. We expect to submit an IND application for azvudine + CTX combination therapy for the treatment of lymphoma in the second half of 2026.

Rapidly advance our other Core Products and drug candidates through internal research

We plan to continue advancing the clinical development of our preclinical- or clinical-stage drug candidates through internal research and improve our research conversion capabilities leveraging our track record in clinical development and experienced R&D team. Specifically, in addition to research and development of azvudine, we (i) completed the Phase I clinical trial of CL-197, our Core Product, for HIV treatment in China in March 2025, obtained ethics committee approval for the Phase IIa clinical trial in September 2025, and expect to complete this Phase IIa trial and initiate Phase IIb trial in 2026; (ii) have completed the Phase I clinical trial of dosimertinib, our Core Product, for the treatment of NSCLC in China, had first patient enrolled for the Phase II trial in June 2025 and expect to complete the Phase II trial in 2026; and (iii) expect to complete the respective preclinical studies of ZSSW-136 and MTB-1806 and submit IND applications in 2026.

Continue the expansion of our R&D platforms and expand our product pipeline

We plan to continue to expand the establishment of our R&D platforms, such as our highly-selective new nucleoside-like broad-spectrum antitumor research and development platform, and our TOPO1 inhibitor and XDC drug research and development platform. We will further expand our product pipeline based on our existing platforms and technologies to meet unmet medical needs, and quickly advance the R&D of antiviral drugs and anti-tumor drugs, in particular to potentially address the drug resistance issue to existing therapeutic options. In addition, we will continue to explore the indication expansion and combination therapies of azvudine with other drugs for the treatment of cancer and HIV infection, as well as further advancing the ongoing drug discovery for the treatment of cancer.

Enhance our commercialization capability to support future commercial activities

For the approved indications of azvudine (HIV and COVID-19), we plan to further enhance the professional and promotional capabilities of our in-house sales and marketing team, strengthen hospital channel coverage, recruit, train and manage our CSOs to enhance marketing effectiveness. We also seek to improve and optimize the on-line e-commerce channel and off-line distribution channels to improve product accessibility. Furthermore, we will continue to improve the evidence-based medical evidence of our products to promote their widespread use and long-term development in the market. We will also prepare for the future expansion of azvudine's indications and the commercialization of other drug candidates to ensure that new products can be quickly and efficiently brought to market.

BUSINESS

Strengthen talent team building through internal cultivation and recruitment

We believe that a team of outstanding and professional talent is core for a biotech company to remain competitive. We will continue to strengthen our talent team building through internal cultivation and recruitment.

With respect to internal cultivation, we will continuously improve professionalism of our employees through systematic training, so that they can achieve their full potential in their respective roles and provide a solid foundation for our effective operations. With respect to recruitment, we will continue to expand our R&D team to meet our growing R&D needs. We also plan to further supplement our legal and financial team to ensure the sustainable growth of our business. In addition, we plan to provide competitive compensation packages to attract new and retain outstanding employees.

OUR PRODUCT PORTFOLIO

We have built a comprehensive drug portfolio, primarily consisting of seven drug candidates, being (i) azvudine, our Core Product, a conditionally approved drug for the treatment of HIV infection and COVID-19 in China, centered on which we are developing a monotherapy for the treatment of multiple myeloma, lymphoma and acute leukemia, a monotherapy for the treatment of immunological non-responders (INRs) in HIV-infected patients, as well as four combination therapies including azvudine + anti-PD-1 for the treatment of liver cancer and colorectal cancer, azvudine + dosimertinib for the treatment of NSCLC, azvudine/CL-197 for the treatment of HIV and azvudine + CTX for the treatment of lymphoma; (ii) CL-197, our Core Product, for the long-acting treatment of HIV infection; (iii) dosimertinib, our Core Product, for the treatment of NSCLC; (iv) ZSSW-136 for the treatment of malignant tumor; (v) MTB-1806 for the treatment of AIS; (vi) ZS-2004 for the treatment of solid tumors; and (vii) ZS-1004 for the treatment of solid tumors.

Azvudine—Our Core Product

HIV Infection

Azvudine has been listed as a National Major Science and Technology Project in China (major new drug development), and was included in the 2021 and 2024 editions of China HIV Diagnosis and Treatment Guidelines after its NMPA approval. It is a novel dual-target nucleoside-based antiviral drug that inhibits both reverse transcriptase, and accessory protein Vif. We obtained a conditional approval from the NMPA for azvudine as an oral medication for HIV-1 infected patients, which constitute over 90% of all HIV-infected patients globally, over age 18 and with high viral load (over 100,000 copies/ml of HIV-1 RNA). As an NRTI, azvudine could function as the backbone medication and work in combination with antiretroviral drugs of different mechanisms to form various two-drug or three-drug ART regimens.

Azvudine was originally discovered and developed by Zhengzhou University for HIV infection treatment. We acquired intellectual property rights in azvudine in June 2013 pursuant to a technology transfer agreement dated December 16, 2011 and a supplemental agreement dated May 14, 2013. See “—Our Technology Transfer Arrangements and Collaborations—Zhengzhou University Technology Transfer Agreement.” We received approval from the NMPA in 2013 to conduct a Phase I clinical trial for azvudine for treating HIV infection and commenced such Phase I clinical trial in July 2014. We completed the Phase I clinical trial in June 2015 and received approval from the NMPA in the same year to conduct a Phase II clinical trial for azvudine for treating HIV infection. We commenced Phase II clinical trial in October 2017 and completed such trial in January 2019. We subsequently obtained a conditional approval of azvudine from the NMPA for treating HIV infection in July 2021. We initiated the post-approval Phase III clinical trial in June 2022 and completed patient enrollment in August 2023. We completed the last visit of the last patient for the Phase III clinical trial in June 2025 and completed the CSR in April 2026. Each of the completed clinical trials of azvudine for the treatment of HIV infection has met its primary and secondary endpoints, and there was no deviation from the clinical trial protocol. We have submitted an application for a conversion from conditional approval to a regular approval in April 2026, and expect to obtain the regular approval in the first half of 2027.

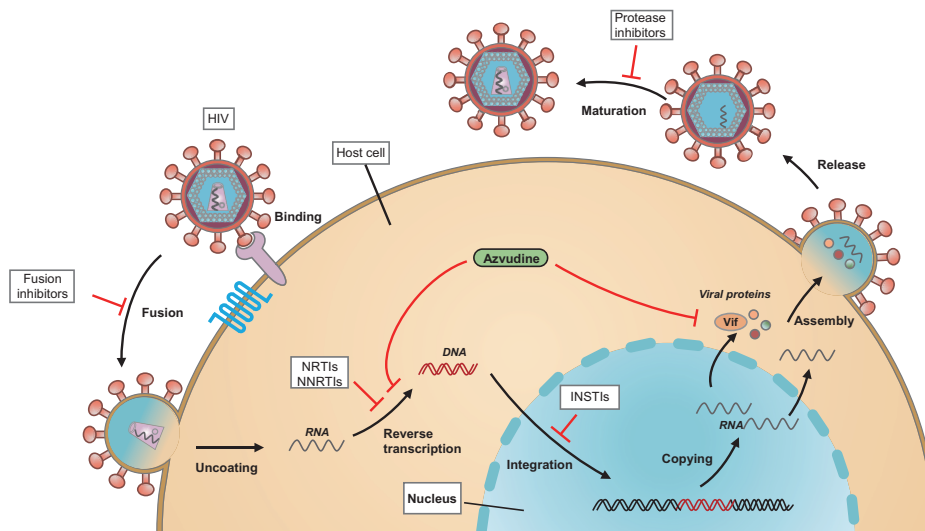
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Mechanism of Action

The life cycle of HIV includes multiple steps, including binding to a host CD4⁺ T cell, fusion with the host cell membrane, uncoating, reverse transcription (RTn), integration into DNA of the host cell, copying, assembling viral components made inside the host cell and releasing new virus. The essential step of RTn requires reverse transcriptase (RT) to convert the viral genetic material, HIV RNA, into HIV DNA in preparation for integration into the host cell DNA.

Azvadine, as an NRTI, functioning at the active site of RT, inhibits RT activities and acts as a DNA chain-terminator to interrupt HIV replication. In addition to inhibition of HIV RT, azvadine also acts as a Vif inhibitor by targeting the Vif-containing E3 ubiquitin ligase complex, blocks the Vif-induced degradation of A3G and restores A3G expression and antiviral activity in CD4⁺ T cells. As a result, azvadine is capable of directly inhibiting viral replication, being an NRTI, while enhancing the patient's own antiviral capabilities as a Vif inhibitor. Dual-mechanism drugs only become ineffective and induce drug resistance when both viral targets mutate simultaneously. The probability of simultaneous mutation at both targets is significantly lower than that of single-target mutation.

With its dual targets, azvadine offers two mechanisms of action in one drug. The following diagram illustrates the mechanisms of action of azvadine for the treatment of HIV infection:



Source: Company information

Market Opportunity and Competition

The majority of HIV drugs in China's market are single-agent antiretroviral drugs instead of composite drugs containing multiple ART agents, which are more accessible in developed markets. Single-agent antiretroviral drugs from a different class, such as NNRTIs or INSTIs, are not considered substitutes or competitors of azvadine, because as an NRTI, azvadine could work in combination with drugs of different mechanisms to form various cART regimens. See "Industry Overview—Antiviral Drug Market—The HIV Drug Market—Competitive Landscape of HIV Drugs" for details of the competitive landscape of marketed NRTI drugs for treatment of HIV infection in China.

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We believe azvudine has the potential to become a primary HIV NRTI with the following characteristics:

- *Good Efficacy.* In our Phase II clinical trial of azvudine for the treatment of HIV infection, daily administration of azvudine, in combination with two other antiretroviral drugs as a cART regimen, showed anti-HIV-1 efficacy and was able to inhibit HIV-1 replication. In the trial, the clinical efficacy of daily administration of 3 mg azvudine was comparable to that of daily administration of 300 mg lamivudine. Lamivudine is a nucleoside analogue commonly used in first-line combination therapy for treating HIV infection.
- *Lower risk of drug resistance.* As nucleoside analogues are an important class of antiviral agents commonly used in the treatment of HIV infection, over 83.1% of HIV-infected patients with viral load exceeding 1,000 copies/ml developed resistance to the NRTIs in their regimens. However, in an *in vitro* study, azvudine showed potent inhibition on multiple NRTI-resistant HIV strains and activity against M184V mutation. In addition, due to its dual-target mechanism of action, we believe azvudine is less likely to result in drug-resistance compared to single-target NRTIs.
- *Oral administration and extended dosing under evaluation.* Our recent animal studies showed that the active form of azvudine could be detected in peripheral blood mononuclear cells (PBMC) 168 hours after oral gavage administration. These findings are being further evaluated to assess the pharmacokinetic characteristics of azvudine and its potential suitability for oral administration with extended dosing intervals in combination therapy settings for HIV-related research.

Summary of Clinical Trials

As of the Latest Practicable Date, we had completed Phase I and Phase II clinical trials for azvudine as a treatment for HIV infection in China. As of the same date, we had also completed the last visit of the last patient under the Phase III clinical trial for azvudine for the indication since June 2022 as required by the conditional NMPA approval and completed the CSR in April 2026. Please see “—Summary of Our Post-approval Clinical Trial” below for further details.

Phase II Clinical Trial

The Phase II clinical trial was a multi-center, randomized, double-blind double-dummy, positive control and dose-exploration clinical study in China to assess the safety and efficacy of azvudine in treating HIV infection.

- *Study design.* The Phase II clinical trial planned to enroll 172 patients. According to the plan, all patients would be randomly assigned to a 2 mg/day dose group, a 3 mg/day dose group, a 4 mg/day dose group and a control group (receiving lamivudine) at a ratio of 1:1:1:1. The objective was to evaluate the safety and efficacy of azvudine in combination with tenofovir disoproxil fumarate (TDF), an NRTI, and efavirenz (EFV), an NNRTI, in treating treatment-naïve HIV-infected patients.

The Phase II clinical trial would include a screening period (up to 30 days) and a treatment period (48 weeks). Patients in the azvudine groups would receive daily oral administration of azvudine at the dosage level corresponding to their dose groups along with 300 mg TDF and 600 mg EFV in a fasted state for 48 weeks. Patients in the lamivudine control group would receive daily oral administration of 300 mg lamivudine along with 300 mg TDF and 600 mg EFV in a fasted state. The primary endpoint is the proportion of patients who have less than 50 copies/ml of HIV-1 RNA after the 48-week treatment. Secondary endpoints include change in log value of HIV-1 RNA viral load after the treatment, the number of patients whose HIV-1 RNA decreased by not less than 1 log₁₀ from baseline value and change in CD4⁺ T cell counts after the treatment.

- *Trial status.* The Phase II clinical trial was initiated in October 2017 and completed in January 2019. A total of 172 patients were enrolled, including 43 patients in each group. 155 patients completed the trial and were included in the per protocol set (PPS) analysis, including 36 patients in the 2 mg/day dose group, 39 patients in the 3 mg/day dose group, 40 patients in the 4 mg/day dose group and 40 patients in the lamivudine control group.

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- *Efficacy.* Daily oral administration of azvudine (at the dosage level of 2 mg/3 mg/4 mg), in combination with TDF and EFV, showed anti-HIV-1 efficacy and was able to inhibit HIV-1 replication. In the FAS analysis, the proportion of patients with less than 50 copies/ml of HIV-1 RNA after the 48-week treatment was 88.1%, 92.9%, 93.0%, and 90.7% in the 2mg, 3mg, 4mg, and the lamivudine control groups, respectively; while in the PPS analysis, the proportion of patients with less than 50 copies/ml of HIV-1 RNA after the 48-week treatment was 97.2% (35 out of 36 patients), 100.0% (39 out of 39 patients), 100.0% (40 out of 40 patients) and 97.5% (39 out of 40 patients) in the 2 mg/day, 3 mg/day and 4 mg/day dose groups and the lamivudine control group, respectively. There was no statistically significant difference among the azvudine groups and the lamivudine control group ($P>0.05$).

On secondary endpoints, the HIV-1 RNA level of patients in all groups decreased quickly, with a majority of patients experiencing a 1.5 to 3 $\log_{10}$ copies/ml decrease in HIV-1 RNA after 4 to 12 weeks of treatment and remaining at this level till the end of the 48-week treatment. In the PPS analysis, the proportion of patients whose HIV-1 RNA level decreased by not less than 1 $\log_{10}$ was 100.0% for all groups. The CD4⁺ T cell counts for all patients increased after treatment. There were no statistically significant differences among the azvudine groups and the lamivudine control group on secondary endpoints.

- *Safety.* Azvudine demonstrated a good safety profile for long-term administration in the Phase II clinical trial. There were no statistically significant differences among the azvudine groups and the lamivudine control group in terms of overall occurrence rate and severity of AEs. Most of the AEs occurred in this study were mainly of grade 1 and grade 2. Only one subject in the lamivudine control group experienced an SAE that was unrelated to azvudine. Only one subject in the 3 mg group and one subject in the lamivudine control group experienced AEs of grade 4 that were unrelated to azvudine. The table below sets out a summary of AEs in the trial, with a total of 170 patients (the number of patients who received at least one administration of tested drug) included in the analysis.
- *Conclusion.* Daily oral administration of azvudine (at the dosage level of 2 mg, 3 mg and 4 mg) in combination with TDF and EFV for 48 weeks in HIV-infected patients who had not received ART significantly inhibited HIV-1 replication and showed a good safety profile. Patients showed significant decreases in HIV-1 RNA levels. There were no statistically significant differences among the azvudine groups and the lamivudine control group in terms of efficacy and safety.

Phase I Clinical Trial

Our Phase I clinical trial primarily consisted of two major studies, a single-dose study and a multiple-dose study, on the safety, tolerance and pharmacokinetics of azvudine to better assess its impact on HIV-infected patients.

Single-dose Study

The Phase I single-dose clinical trial was a single-center, open-label and non-controlled single ascending-dose clinical study to evaluate the safety, tolerance and pharmacokinetics of azvudine on HIV-infected patients.

- *Study design.* The trial planned to enroll five groups of eight patients with the first group receiving a starting dose of 1 mg/day and the subsequent four groups receiving an increased dose level of 2 mg/day, 3 mg/day, 4 mg/day and 5 mg/day, respectively. The clinical trial would include a screening period (15 days), a treatment period (one day) and a safety follow-up period (seven days). If half or more than half of the patients in a given dose group have AEs of grade 2 or higher, three additional patients will be added to this dose group. If less than half of the patients have AEs of grade 2 or higher, the trial will move to the next dose level. Each subject will receive only one corresponding dose of azvudine, and the trial can proceed from one dose level to the next only if the previous dose level group completes the trial, including the safety follow-up period, and the safety and tolerance of the previous dose level is confirmed.
- *Trial status.* The clinical trial was initiated in June 2014 and completed in June 2015. A total of 40 subjects completed the trial, with eight each in the 1 mg/day dose group, 2 mg/day dose group, 3 mg/day dose group, 4 mg/day dose group and 5 mg/day dose group, respectively.

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- *Safety.* In the clinical trial, the dose escalation reached 5 mg. Nine patients experienced 11 AEs associated with azvudine (one in the 1 mg group, two in the 2 mg group and six in the 4 mg group). All AEs were of grade 1, comprising, in descending order of frequency, dizziness (4 out of 11, 36.36%), nausea (3 out of 11, 27.27%), fever (2 out of 11, 18.18%), diarrhea (2 out of 11, 18.18%) and vomiting (1 out of 11, 9.09%). There were no AEs in the 3 mg and 5 mg groups. None of the patients experienced SAE.
- *Pharmacokinetics.* The plasma drug concentration of azvudine was relatively low in HIV-infected patients after a single administration of azvudine. The AUC of the 3 mg, 4 mg and 5 mg groups gradually increased as the dose level increased. The 4 mg dose group had the highest mean C_{max} (which represents the maximum drug concentration in plasma) value, with no statistically significant difference from the 3 mg group or the 5 mg group. Azvudine was absorbed relatively quickly and eliminated relatively slowly in the body. Excretion within 12 hours after administration accounted for more than 70% of the total excretion within 24 hours after administration.
- *Conclusion.* A single administration of azvudine at the dosage level of 1 mg to 5 mg is safely tolerated in HIV-infected patients. All AEs occurred were mild, mainly manifesting as fever, dizziness, nausea and diarrhea, all of which had been reported with similar anti-HIV drugs currently on the market and patients can recover with or without symptomatic treatment. A multiple-dose study of the tolerability, safety and pharmacokinetics of azvudine could be conducted.

Multiple-dose Study

The Phase I multi-dose clinical trial was a single-center, open-label and non-controlled multiple-dose clinical study to evaluate the safety, tolerance and pharmacokinetics of azvudine on HIV-infected patients.

- *Study design.* The study was designed with two groups of eight patients. The first group (the BID group) would receive 2 mg azvudine BID (*i.e.*, twice daily) with a 12-hour interval between doses for seven days and the second group (the QD group) would receive 4 mg azvudine QD (*i.e.*, once daily) in a fasted state for seven days. If four or more patients in the first group experienced AE of grade 2 or above, three additional patients would need to be enrolled in the group. If one or more of such three additional patients experienced AE of grade 2 or above, the trial would be terminated. The trial would proceed to the QD group only if the BID group completed the test. If four or more patients in the second group experienced AE of grade 2 or above, then a test of the 3 mg/day dose level, administered in a single dose, would need to be conducted.
- *Trial status.* The clinical trial was initiated in January 2015 and completed in June 2015. A total of 16 subjects completed the trial, with eight each in the BID group and QD group.
- *Safety.* Three patients in the BID group had five AEs and two patients in the QD group had two AEs. Only one AE in the QD group was deemed to be likely related to the drug, mainly manifesting as decreased absolute neutrophil counts (ANC). No SAEs occurred during the trial. The AEs occurred were, in descending order of occurrence rate, elevated total bilirubin (2/7, 28.57%), decreased ANC (1/7, 14.29%), elevated aspartate aminotransferase (AST) (1/7, 14.29%), elevated blood glucose (1/7, 14.29%), cold (1/7, 14.29%) and alveolar abscess (1/7, 14.29%).
- *Efficacy.* There were significant decreases ($p<0.05$) in HIV viral load in patients of both the BID group and the QD group after drug administration, but the difference between the two groups was not statistically significant ($p>0.05$). Patients in both the BID group and the QD group experienced increases in $CD4^+$ T cell counts, but the increases were not statistically significant. There was no statistically significant difference between the two groups in terms of changes in $CD4^+$ T cell counts.
- *Pharmacokinetics.* After seven consecutive days of administration of azvudine, there were no statistically significant differences between the C_{max} , T_{max} (which represents the time it takes for a drug to reach C_{max}), MRT (mean residence time, which represents the average time a molecule stays in the body) and $T_{1/2}$ (half life) for the first drug administration and those for the last drug administration in the BID group. There were no statistically significant differences between the T_{max} , C_{max} , MRT, $T_{1/2}$ and AUC for the first drug administration and those for the last drug administration in the QD group. The T_{max} , C_{max} and AUC for the last drug administration were higher in the QD group than in the BID group, but there was no statistically significant difference.

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- *Conclusion.* The results of the trial showed a good tolerability and safety profile for azvudine with multiple drug administrations. Azvudine showed anti-HIV-1 activity in the trial. A dose-exploration study with a large sample size to further evaluate the efficacy and safety of azvudine in combination with other drugs could be conducted.

Other Clinical Studies

After the Phase I clinical trial, we conducted additional clinical trials to assess the pharmacokinetics of azvudine in postprandial (after meal) administration, the safety of azvudine for treatment-naïve patients and azvudine's drug interaction with other drugs.

Postprandial Administration Study

We conducted a randomized and cross-administered clinical study with two cycles. The purpose of the study was to evaluate the pharmacokinetics of azvudine after postprandial administration. The study was initiated in December 2015 and completed in May 2018. Single administrations of azvudine under fasting condition and under postprandial condition were safely tolerated in healthy subjects. The occurrence rates of AEs for fasting and postprandial administrations of azvudine were similar.

Multiple-Dose Study in Treatment-Naïve Patients

We conducted a single-center, non-controlled and open-label clinical study to evaluate the safety of azvudine for treatment-naïve patients. The study was initiated in July 2017 and completed in August 2018. Administration of azvudine for seven consecutive days (at the dosage level of 2 mg/day and 3 mg/day) in HIV-infected patients who had not received anti-HIV treatment showed a good safety and tolerability record. There were no SAEs, or AEs that led to withdrawal from the trial. The results also showed that azvudine had good anti-HIV-1 activity and good initial efficacy. A dose-exploration study with a large sample size to further evaluate the efficacy and safety of azvudine in combination with other drugs could be conducted.

Drug-Drug Interaction Studies

We conducted several drug-drug interaction studies of azvudine with other HIV drugs primarily to evaluate PK of azvudine and other drugs in combination administration. The table below summarizes the details of such studies:

Azvudine in combination with	Clinical Trial Overview	Start time (first subject enrolled)	Completion time (CSR report issuance time)	Summary of key results	Whether primary and secondary endpoints have been reached	Whether any deviations from the clinical trial protocol
Tenofovir Disoproxil Fumarate (TDF)	a single-center and open-label clinical study in China to evaluate the pharmacokinetics of azvudine after administration of azvudine in combination with TDF	September 2015	May 2018	- A total of 15 subjects completed the test. - Safety: The occurrence rates of AEs were similar for administration of azvudine or TDF alone and combined administration of the two drugs. - Conclusion: Multiple co-administrations with TDF significantly increased the exposure of azvudine in the subjects. Multiple coadministrations with azvudine had no significant impact on the exposure of TDF in the subjects.	Yes	No

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Azvudine in combination with	Clinical Trial Overview	Start time (first subject enrolled)	Completion time (CSR report issuance time)	Summary of key results	Whether primary and secondary endpoints have been reached	Whether any deviations from the clinical trial protocol
Efavirenz (EFV)	a single-center and open-label clinical study in China to evaluate the pharmacokinetics of azvudine after administration of azvudine (at the dosage level of 4 mg/day) in combination with EFV (at the dosage level of 600 mg/day)	September 2015	May 2018	- A total of 24 subjects completed the test. - Conclusion: Multiple co-administrations with EFV significantly increased the exposure of azvudine in the subjects. There was no conclusion as to whether multiple co-administration with azvudine had any impact on the pharmacokinetics of EFV.	Yes	No
Tenofovir Alafenamide Fumarate (TAF)	This single-center, randomized, open-label, three-period, three-crossover drug interaction study conducted in China aims to evaluate the pharmacokinetic effects of azvudine combined with TAF in humans.	March 2022	August 2023	- A total of 15 patients were enrolled. - Pharmacokinetics: Analysis of the effect of TAF on azvudine showed that after multiple oral administrations of azvudine and TAF to healthy subjects, azvudine had no effect on the steady-state C_{max} and AUC of TAF. TAF had no effect on the steady-state C_{max} and AUC of azvudine. - Safety: No serious adverse events, serious adverse reactions, or adverse events leading to dropouts occurred in any of the subjects during the study. - Conclusion: Considering the plasma exposure and pharmacological effects of azvudine and TAF, after multiple oral administrations of azvudine and TAF in healthy subjects, azvudine had no effect on the steady-state C_{max} and AUC of TAF. TAF also had no effect on the steady-state C_{max} and AUC of azvudine. Safety analysis showed that azvudine and TAF, alone or in combination, were well-safe and tolerable.	Yes	No

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Azvodine in combination with	Clinical Trial Overview	Start time (first subject enrolled)	Completion time (CSR report issuance time)	Summary of key results	Whether primary and secondary endpoints have been reached	Whether any deviations from the clinical trial protocol
dolutegravir sodium tablets (DTG)	the mutual pharmacokinetic effects of azvodine and DTG in humans after administration.	December 2021	September 2022	- A total of 16 patients were enrolled (1 patient withdrew before starting medication). - Pharmacokinetics: In healthy subjects, after multiple concurrent oral administrations of azvodine and DTG, azvodine had no effect on the steady-state C_{max} and AUC of DTG. DTG had a slight effect on the steady-state C_{max} and AUC of azvodine, increasing them by 37.0% and 20.3%, respectively. - Safety: No serious adverse events, serious adverse reactions, adverse events leading to death, or important adverse events occurred in any of the subjects during the study. - Conclusion: In healthy subjects, after multiple oral administrations of azvodine and DTG, azvodine had no effect on the steady-state C_{max} and AUC of DTG. DTG slightly affected the steady-state C_{max} and AUC of azvodine, increasing them by 37.0% and 20.3%, respectively. Safety analysis showed that azvodine and DTG, alone or in combination, were safe and well-tolerated.	Yes	No
Itraconazole (ICZ)	the mutual pharmacokinetic effects of azvodine and ICZ in humans after administration.	February 2022	March 2023	- A total of 15 patients were enrolled. - Pharmacokinetics: Multiple oral administrations of potent ICZ in healthy subjects. The 3A4 inhibitor itraconazole had no significant effect on the steady-state C_{max} and AUC of azvodine. Azvodine also had no significant effect on the steady-state C_{max} and AUC of itraconazole. - Safety: No serious adverse events, serious adverse reactions, adverse events leading to death, or important adverse events occurred in any of the subjects during the study. - ICZ in healthy subjects had no significant effect on the steady-state C_{max} and AUC of azvodine. Azvodine had no significant effect on the steady-state C_{max} and AUC of ICZ. Safety analysis showed that azvodine and ICZ, alone or in combination, had good safety and tolerability.	Yes	No

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Azvodine in combination with	Clinical Trial Overview	Start time (first subject enrolled)	Completion time (CSR report issuance time)	Summary of key results	Whether primary and secondary endpoints have been reached	Whether any deviations from the clinical trial protocol
Rifampin (RIF)	This single-center, randomized, open-label, three-period, three-crossover drug interaction study conducted in China aims to evaluate the pharmacokinetic effects of azvodine combined with RIF in humans.	December 2021	October 2023	- A total of 15 patients were enrolled. - Pharmacokinetics: In healthy subjects, repeated oral administration of RIF had a slight effect on the steady-state C_{max} and AUC of azvodine, increasing them by 57.8% and 23.8%, respectively. Azvodine had no effect on the steady-state C_{max} and AUC of RIF. - Safety: In the azvodine + RIF group, there was one serious adverse event, which was upper gastrointestinal bleeding that required hospitalization. The patient recovered after drug treatment. No adverse events that led to death occurred. - RIF in healthy subjects had a slight effect on the steady-state C_{max} and AUC of azvodine, increasing them by 57.8% and 23.8%, respectively. Azvodine had no effect on the steady-state C_{max} and AUC of RIF. Safety analysis showed that azvodine and RIF, used alone or in combination, had good safety and tolerability.	Yes	No
Rilpivirine (RPV)	the mutual pharmacokinetic effects of azvodine and RPV in humans after administration.	February 2022	January 2023	- A total of 15 patients were enrolled (5 in each group). - Pharmacokinetics: In healthy subjects, after multiple concurrent oral administrations of azvodine and RPV, azvodine had no effect on the steady-state C_{max} and AUC of RPV. RPV also had no effect on the steady-state C_{max} and AUC of azvodine. - Safety: No serious adverse events, serious adverse reactions, adverse events leading to death, or important adverse events occurred in any of the subjects during the study. - Conclusion: In healthy subjects, after multiple oral administrations of azvodine and RPV, azvodine had no effect on the steady-state C_{max} and AUC of RPV. RPV also had no effect on the steady-state C_{max} and AUC of azvodine. Safety analysis showed that azvodine and RPV, alone or in combination, were safe and well-tolerated.	Yes	No

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Summary of Our Post-approval Clinical Trial

We obtained a conditional approval for azvudine for treatment of HIV infection from the NMPA in July 2021. While we are authorized to market azvudine for the treatment of HIV infection in China, we are required to conduct a post-approval Phase III clinical trial and submit the clinical study report to the NMPA before July 2026. In this post-approval clinical trial, we aim to further demonstrate the safety and efficacy profile of azvudine when administered together with TDF and EFV for treatment of HIV-infected treatment-naïve patients and the trial will be conducted in accordance with the requirements of the NMPA and relevant regulations.

We initiated the Phase III clinical trial in June 2022. The Phase III clinical trial is a multi-center, randomized, double-blind, double-dummy and active-controlled clinical study in China. We have enrolled 720 patients in 14 clinical centers who meet the criteria, and randomly assign them to the test group (the azvudine group) and the control group (the lamivudine group) in the proportion of 1:1. The number of patients in the azvudine group and the lamivudine group is 360 and 360, respectively. The patients in the azvudine group receive daily administration of 3 mg azvudine in combination with 300 mg TDF and 400 mg EFV, as well as a lamivudine dummy tablet. The patients in the lamivudine group receive daily administration of 300 mg lamivudine in combination with 300 mg TDF and 400 mg EFV, as well as an azvudine dummy tablet. The choice of the 3 mg/day dosage level is based on the conclusion from our previous clinical trials that 3 mg/day was well tolerated with oral administration and had shown clear efficacy. The primary endpoint is the proportion of patients with less than 50 copies/ml of HIV-1 RNA at week 48 of the treatment. Secondary endpoints include the proportion of patients with less than 50 copies/ml of HIV-1 RNA at week 24 and week 96 of the treatment and the change in patients' number of CD4⁺ T cells against the baseline CD4⁺ T cell count at week 48 and week 96 of the treatment. Each treatment cycle lasts 96 weeks unless subjects experience disease progression, intolerable AE or withdraw their consents.

We completed patient enrollment in August 2023, completed the last visit of the last patient in June 2025 and completed the CSR in April 2026. We have submitted an application for a conversion from conditional approval to a regular approval in April 2026, and expect to obtain the regular approval in the first half of 2027.

Near-term Plans

We received a conditional approval of azvudine for treatment of HIV infection from the NMPA in July 2021 and will continue its commercialization in China. See “—Commercialization” for details. As of the Latest Practicable Date, we had completed the last visit of the last patient under the post-approval Phase III clinical trial of azvudine for the HIV indication in China, and completed the CSR in April 2026.

Material Regulatory Communications

Our communications with the CDE relating to the *Guiding Principles for Clinical Virological Studies and Data Submission of Anti-HIV-1 Infection Drugs (Draft for Comment)* included providing feedback and participating in the relevant expert consultation meeting in August 2024. The final *Guiding Principles for Clinical Drug Resistance Studies and Data Submission of Anti-HIV Infection Drugs* were promulgated by the CDE in July 2025. The implementation of these guiding principles does not have any impact on our ongoing HIV-related clinical studies.

Our communications with the NMPA relating to the advancement of the development of azvudine for treatment of HIV infection can be divided into three stages: (i) IND clinical trial application and review; (ii) conclusion of the Phase I clinical trial and application for the initiation of the Phase II clinical trial; and (iii) application for NDA approval.

- We submitted an IND clinical trial application for azvudine for treatment of HIV infection and received approval from the NMPA in April 2013 for the commencement of a Phase I clinical trial for azvudine for treatment of HIV infection in China.

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- After the completion of our Phase I clinical trial, the NMPA reviewed our Phase I clinical trial results and authorized a Phase II clinical trial for azvudine for treatment of HIV infection in China in December 2015.
- Subsequent to the completion of the Phase II clinical trial in January 2019, the NMPA reviewed our materials seeking NDA approval for azvudine for the treatment of HIV infection in China and granted a conditional approval in July 2021. Pursuant to the conditional approval, we could commence sales of azvudine for treatment of HIV infection and shall conduct a Phase III clinical trial, submit safety reports periodically and submit a Phase III clinical trial report within five years from the date of approval.

Other than the above, we have not had any material communications with the NMPA for azvudine for treatment of HIV infection. As of the Latest Practicable Date, no material adverse change had occurred with respect to the review or approval process of azvudine for the treatment of HIV infection.

Our further development of azvudine for additional indications, such as COVID-19, solid tumors and blood cancer, including eventual application for NMPA approval, will not be impacted by the fulfillment, or lack thereof, of the conditions for the approval of azvudine for the HIV indication because they will be pursued as separate regulatory processes.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET AZVUDINE FOR THE TREATMENT OF HIV INFECTION SUCCESSFULLY.

COVID-19

Leveraging its broad-spectrum antiviral activity, we have expanded the indication of azvudine, making azvudine an effective, safe and convenient oral treatment of COVID-19. As a nucleoside analogue, azvudine, through its incorporation by RdRp, terminates RNA synthesis and thus interrupts the replication of RNA viruses, including SARS-CoV-2, the virus causing COVID-19. In addition, it not only suppresses viral replication, but also targets both the symptom and the underlying cause by enhancing immune function. With a relatively low price per bottle, azvudine is an affordable treatment option with low economic burden and has significantly improved treatment accessibility and affordability. We believe that azvudine can remain an effective medication to treat COVID-19 given its feature of convenient administration regimen, low estimated treatment costs and potential for maintaining efficacy toward new variants.

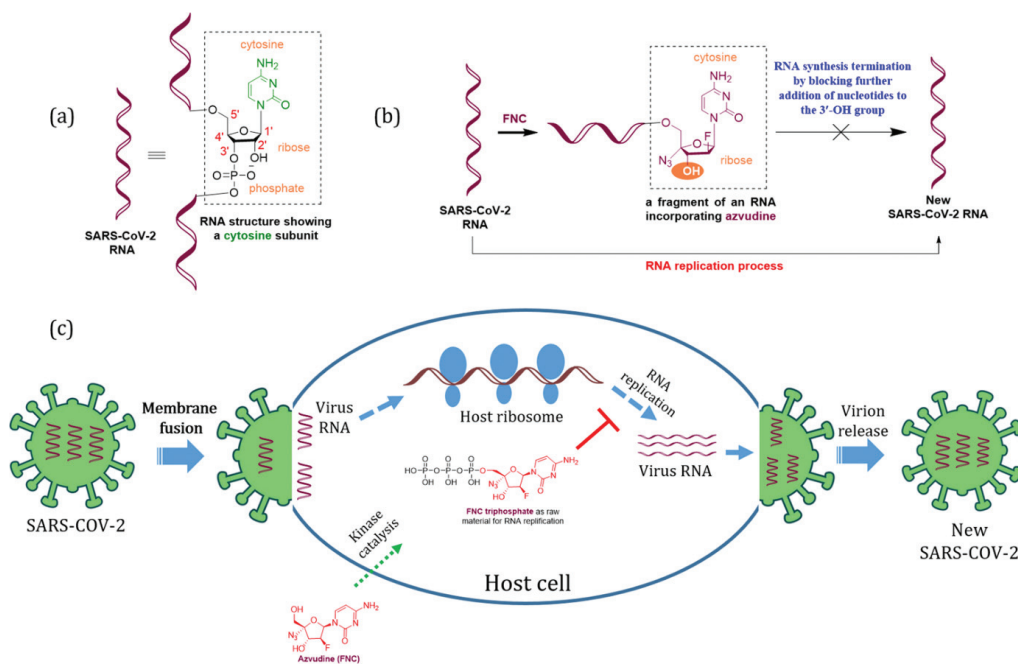
Based on (i) the safety profile of azvudine demonstrated in its Phase I and Phase II clinical trials for treating HIV infection; and (ii) the efficacy profile demonstrated in preclinical *in vitro* studies and a preliminary clinical trial of azvudine as a treatment for COVID-19, we submitted an IND application to the NMPA in April 2020 to directly initiate a Phase III clinical trial for azvudine for treating COVID-19 in China and received approval in the same month. We completed such trial in March 2022. In July 2022, we obtained a conditional approval from the NMPA for indication expansion of azvudine to the treatment of common COVID-19 in adults. Pursuant to the approval, we could commence commercial sales of azvudine for the COVID-19 indication and shall (i) conduct pharmacodynamic studies of azvudine against mutant variants of the SARS-CoV-2 virus; (ii) actively progress ongoing clinical trials of azvudine and submit trial reports upon completion; (iii) continue to collect efficacy and safety clinical data post-approval; and (iv) submit the required materials within three years of approval.

We have completed all of the required R&D work and submitted an application for a conversion of the conditional approval to a regular approval in July 2025, and we expect to obtain the regular approval in the first half of 2026. We have also collaborated with third parties to conduct Phase III clinical trials of azvudine for treating COVID-19 in Russia and Brazil. See “—Our Technology Transfer Arrangements and Collaborations—Beijing Union Collaboration Agreements in Russia and Ukraine” for further details. In addition, as an increasing global population has been experiencing long COVID symptoms following COVID-19 illness, we plan to explore the potential of azvudine for treating long COVID in overseas markets.

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Mechanism of Action

SARS-CoV-2, a positive-sense single-stranded RNA virus, utilizes nucleosides and nucleotides for RNA synthesis. Azvudine, a nucleoside analogue, mimics natural nucleosides inside the host cells and is transformed into corresponding active nucleoside triphosphates through kinase catalysis, which are then incorporated into virus RNA during RNA synthesis by RdRp, thereby preventing incoming nucleotides from being added to the RNA chain and terminating RNA chain elongation and virus replication. In addition, as a nucleoside-based antiviral agent, azvudine also inhibits the activity of RdRp, which are crucial for viral replication. Moreover, azvudine and its triphosphate are largely concentrated in PBMCs and the thymus suggesting an immune-targeting nature of azvudine on top of its antiviral effect. The inhibition of SARS-CoV-2 replication in the thymus might protect the host immune system from viral attack and promote host T cell immunity against viruses. The following diagram illustrate the mechanism of action of azvudine for the treatment of COVID-19:



Source: Company information

Market Opportunity and Competition

The main treatment option currently for COVID-19 is antiviral drugs, primarily including RdRp inhibitors. According to Frost & Sullivan, antiviral therapy has shown great efficacy in treating mild-to-moderate cases and has the potential to maintain high efficacy in suppression of variants due to the different mechanisms of action. See “Industry Overview—Antiviral Drug Market—The COVID-19 Drug Market—Competitive Landscape of Oral Treatment of COVID-19” for details of the competitive landscape of marketed oral antiviral COVID-19 treatments.

The commercialization outlook of azvudine for COVID-19 remains subject to material uncertainty. With the change in the COVID-19 situation in China, including a decline in the number of infections driven by strengthened public health management, vaccination and population immunity, the actual clinical demand for COVID-19 treatment may fluctuate and remains uncertain going forward. In addition, future changes in national policies, procurement arrangements, reimbursement policies and clinical treatment guidelines may further affect the market environment of COVID-19 drugs, bringing uncertainty to the potential sales performance and contribution of azvudine for the COVID-19 indication.

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Summary of Clinical Trials

Phase III Clinical Trial in China

The Phase III clinical trial was a multi-center, randomized, double-blind and parallel-controlled clinical study evaluating the safety and efficacy of oral administration of azvudine in patients with mild to common cases of COVID-19. We obtained approval for our Phase III clinical trial from the NMPA in April 2020 and commenced the Phase III clinical trial in June 2020. This trial was completed in March 2022. The primary endpoint* of this study has been met, demonstrating the efficacy of azvudine. According to secondary endpoints, there was no statistically significant difference between the study group and the control group. There was no deviation from the clinical trial protocol.

- *Study design.* We planned to enroll 342 patients from 11 sites nationwide and randomly assign them to the test group and the control group in the proportion of 1:1. The number of patients in the test group and the control group would be 171 and 171, respectively. The patients in the test group would receive standard of care treatment and daily administration of azvudine at 5 mg/day, a dose level with demonstrated efficacy and safety record in previous studies, for up to 14 days, while the patients in the control group would receive the standard of care treatment in accordance with the government guideline and placebo tablet. The primary endpoints for this trial were change in viral load at day 7 and day 14 of treatment. The secondary endpoints included the rate of and time for nucleic acid negative conversion, pulmonary imaging improvement, body temperature normalization, improvement in respiratory tract signs and symptoms and improvement in other symptoms; change in blood oxygen indications; and need for respiratory support.
- *Trial status.* The Phase III clinical trial was initiated in June 2020 and completed in March 2022. A total of 348 patients were enrolled and 298 patients constituted the full analysis set (FAS), including 150 patients in the test group and 148 patients in the control group.
- *Efficacy.* To adapt to the evolvement of patients' clinical manifestations caused by new variants of the virus, we conducted additional cluster analyses based on patient baseline viral load. There was statistically significant differences between the two groups in terms of changes in viral load on day 5. There was no statistical difference between the test group and the control group on secondary endpoints.
- *Safety.* 341 patients were included in the safety analysis. 62 patients in the test group experienced 119 AEs and 76 patients in the control group experienced 175 AEs. Most of the AEs were of grade 1 or grade 2. One patient in the test group had one AE of grade 3 and three patients in the control group had three AEs of grade 3. No patients had AEs of grade 4 or SAEs. There was no statistically significant difference between the test group and the control group in terms of the frequency and severity of AEs.
- *Conclusion.* The trial results demonstrated azvudine's activity in suppressing the SARS-CoV-2 virus, especially in patients with a baseline viral load of not less than 3 log₁₀, and azvudine's overall good safety profile at the dose level of 5 mg/day with AEs that were mostly of grade 1 or grade 2. Based on overall safety and efficacy considerations, the recommended dose for azvudine for the treatment of COVID-19 is 5 mg/day.

* The differences in primary endpoints for azvudine COVID-19 across jurisdictions arise from varying regulatory considerations, including scientific, public health, ethical and local practical factors (such as the stage of the pandemic, differences in regulatory approaches and the lack of global established guidelines at the outbreak peak when the clinical trials were initiated). Fundamentally, regulatory authorities assign different priorities to "clinically meaningful benefits" based on their pandemic stages, demographics and medical resources.

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Phase III Clinical Trial in Russia

The Phase III clinical trial in Russia is a multi-center, prospective, randomized, double-blind and placebo-controlled clinical study evaluating the safety and efficacy of oral administration of azvudine in patients with COVID-19. Our partner obtained approval for the Phase III clinical trial from the Ministry of Health of the Russian Federation (Russian MoH) in January 2021 and commenced the Phase III clinical trial in June 2021. This trial was completed in November 2022. The primary endpoint* of this study has been met, demonstrating the efficacy of azvudine. According to secondary endpoints, there was no statistically significant difference between the study group and the control group. There was no deviation from the clinical trial protocol. The data from this trial in Russia is not related to the conditional approval of azvudine for the treatment of COVID-19 in China by the NMPA, and not required for the NMPA's consideration for conversion to a regular approval.

- *Study design.* The primary objective of the Phase III clinical trial is to evaluate the safety and efficacy of azvudine (in comparison with placebo) in patients with COVID-19. We expect to enroll 314 patients (in two groups of 157 patients each) in ten study centers located in Russia. The 157 patients in the test group would receive daily oral administration of 5 mg of azvudine, a dose level with demonstrated efficacy and safety record in previous studies, and the 157 patients in the control group would take placebo tablet every day. The treatment cycle would last 14 days, unless the patient is discharged or withdraws his or her consent, with a follow-up period of up to 31 days. The primary endpoints for this trial are the proportion of patients experiencing alleviation of clinical symptoms on day 7 from the start of the treatment and the median time to achieve such alleviation. The secondary endpoints included patient score, time for viral clearance, proportion of patients experienced symptom alleviation at the end of the follow-up period, proportion of patients experienced addition in patient score of one point or more, and proportion of patients progressed to severe or extremely severe cases.
- *Trial status.* The trial was completed in November 2022. A total of 314 patients were enrolled, with 157 patients in each group. 280 patients (142 in the test group and 138 in the control group) were included in the PPS analysis.
- *Efficacy.* Data from the clinical trial showed that there were statistically significant differences (p-value less than 0.001) between the test group (receiving azvudine) and the control group (receiving placebo) on both primary endpoints. In the PPS analysis, 40.1% (57 out of 142) of the patients who received azvudine treatment, as opposed to 10.9% (15 out of 138) of the patients who received placebo, experienced alleviation of clinical symptoms on day 7 from the start of the treatment. The median time to achieve such alleviation was 9 days for patients in the test group and 12 days for patients in the control group. In terms of secondary endpoints, the patients in the test group had significantly lower average patient score than the patients in the control group on day 7 from the start of the treatment. There was no statistically significant difference between the two groups in terms other secondary endpoints.
- *Safety.* The trial showed a good overall safety and tolerability profile for azvudine. 34 patients in the test group experienced 47 AEs and 35 patients in the control group experienced 50 AEs. The AEs were mostly mild or moderate. No patient in the test group or the control group had any SAE. There was no statistically significant difference between the test group and control group with respect to the frequency and severity of AEs.

* The differences in primary endpoints for azvudine COVID-19 across jurisdictions arise from varying regulatory considerations, including scientific, public health, ethical and local practical factors (such as the stage of the pandemic, differences in regulatory approaches and the lack of global established guidelines at the outbreak peak when the clinical trials were initiated). Fundamentally, regulatory authorities assign different priorities to "clinically meaningful benefits" based on their pandemic stages, demographics and medical resources.

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- *Conclusion.* In this trial, the test group showed superior results compared to the control group with respect to the two primary endpoints. Azvudine also demonstrated a good overall safety and tolerability profile, with comparable results between the test group and control group with respect to the frequency and severity of AEs.

Phase III Clinical Trial in Brazil

The Phase III clinical trial in Brazil is a multi-center, randomized, double-blind and placebo-controlled clinical study evaluating the safety and efficacy of oral administration of azvudine in patients with moderate to severe COVID-19. The third party agent responsible for the registration and execution of the trial obtained approval for the Phase III clinical trial from the Brazilian Health Regulatory Agency (ANVISA) in March 2021 and commenced the Phase III clinical trial in June 2021. This trial was initiated for the potential expansion to overseas market. The data from this trial in Brazil is not related to the conditional approval of azvudine for the treatment of COVID-19 in China by the NMPA, and not required for the NMPA's consideration for conversion to a regular approval, as the trial was initiated in light of the then global pandemic development and to support potential overseas regulatory submissions (including to the U.S. FDA) for commercialization in overseas markets.

- *Study design.* The objective of the Phase III clinical trial is to evaluate the safety and efficacy of azvudine (in comparison with placebo) in patients with COVID-19. We expect to enroll 342 patients (in two treatment arms of 171 patients) in five study centers located in Brazil. The 171 patients in control group would take placebo tablets every day and the 171 patients in test group would receive daily oral administration of 5 mg of azvudine, a dose-level with demonstrated efficacy and safety record in previous studies. The treatment cycle would last to 14 days, unless the patient is discharged or withdraws his or her consent, with a follow-up period of up to 60 days. The primary endpoint of this trial is the proportion of patients demonstrating clinical improvement on the WHO clinical progression scale on day 15 from the start of the treatment. Other endpoints include clinical cure rate, time for body temperature normalization and time for improvements in certain symptoms.
- *Trial status.* As of the Latest Practicable Date, the trial was completed.

Other Studies

In February 2020, we entered into a collaboration agreement with People's Hospital of Guangshan County, Henan Province (河南省光山縣人民醫院) to conduct a prospective, randomized, open-label and controlled investigator-initiated clinical trial to assess azvudine's safety and efficacy in treating hospitalized patients with COVID-19. The study was initiated in February 2020 and completed in March 2020, with a total of 20 patients participating and completing the study. The patients were randomly assigned into a test group and a control group at the ratio of 1:1. The patients in the test group received oral administration of azvudine at 5 mg/day and symptomatic treatment till patient discharge, while the patients in the control group received standard antiviral and symptomatic treatment for COVID-19 in accordance with the government guideline. The preliminary clinical results showed that comparing to the standard treatment under the government treatment plan, the azvudine treatment may shorten the nucleic acid negative conversion time, *i.e.*, the time from the start of the treatment to the date of the first negative nucleic acid test result of at least two consecutive negative test results. No drug-related AEs were observed in patients treated with azvudine, while 30% of patients in the control group experienced AEs after treatment with standard antiviral drugs.

In March 2020, we engaged the Institute of Medicinal Biotechnology of the Chinese Academy of Medical Sciences (中國醫學科學院醫藥生物技術研究所) to conduct preclinical studies to assess azvudine's activity against SARS-CoV-2 *in vitro*. The study was completed in April 2020. It evaluated the anti-SARS-CoV-2 efficacy of CL-236, the analogue of azvudine monophosphate, by measuring the number of viral RNA copies and the cytopathic effect (the virus-induced structural changes in host cells) of SARS-CoV-2. The results demonstrated that CL-236 could significantly inhibit viral replication and protect the cells from SARS-CoV-2-caused cell death.

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Near-term Plans

China. We obtained a conditional approval from the NMPA for azvudine for the treatment of common COVID-19 in adults in July 2022 and will continue commercialization in China. See “—Commercialization—Azvudine” for more details. We have completed all of the required R&D work and submitted an application for a conversion of the conditional approval to a regular approval in July 2025, and we expect to obtain the regular approval in the first half of 2026. In addition to HIV and COVID-19, we are also expanding azvudine’s indications, which includes blood cancer, liver cancer, colorectal cancer, and NSCLC. We are currently conducting Phase I clinical trials for azvudine as a monotherapy for the treatment of blood cancers. See “—Cancer Treatment” below for details.

Brazil. As of the Latest Practicable Date, the Phase III clinical trial for azvudine in Brazil had been completed.

Material Regulatory Communications

China

Our communications with the NMPA relating to the development of azvudine for the treatment of COVID-19 can be divided into three stages: (i) indication expansion discussions with the CDE and the local bureau of Henan Medical Products Administration (河南省藥品監督管理局), or the HMPA; (ii) application for initiation of a Phase III clinical trial; and (iii) application for NDA approval.

- In March 2020, we had communications with the CDE regarding indication expansion of azvudine for the treatment of COVID-19 and the relevant review and approval procedure. Pursuant to the relevant laws and regulations governing the drug marketing and clinical trial approvals, an additional and separate clinical trial needs to be conducted for COVID-19 indication expansion of azvudine and a new application for the clinical trial shall be submitted. The research and development of azvudine for the treatment of COVID-19 would not be impacted by our fulfillment, or lack thereof, of the conditions under the NMPA’s conditional approval of azvudine for treating HIV infection or the results of the clinical trial of azvudine for treating HIV infection. Additionally, according to the consultation our PRC Legal Advisors conducted with the Sixth Supervision Bureau of HMPA, given that azvudine indicated for each of HIV infection and COVID-19 is the same molecular compound, the COVID-19 indication will be considered an indication expansion of azvudine and will therefore be treated as the same product. According to our PRC Legal Advisors, the Sixth Supervision Bureau of HMPA is the competent authority for the routine supervision of our PRC operating company, Henan Genuine.
- In April 2020, we submitted an application to the CDE to initiate a Phase III clinical trial for azvudine for the treatment of COVID-19 based on (i) the safety profile of azvudine demonstrated in the Phase I and Phase II clinical trials of azvudine for HIV treatment; and (ii) the efficacy profile demonstrated in preclinical *in vitro* studies and a preliminary clinical trial of azvudine as a treatment for COVID-19. In April 2020, we received approval from the NMPA for the Phase III clinical trial for azvudine for treatment of COVID-19 in China.
- In July 2022, we submitted an NDA application to the NMPA for approval of azvudine for the treatment of COVID-19. The NMPA reviewed our materials, including data from the Phase III clinical trials in China and Russia, in accordance with the China Food and Drug Administration Special Review and Approval Procedure for Drugs (《國家食品藥品監督管理局藥品特別審批程序》) and granted a conditional approval for indication expansion of azvudine as a Class 2.4 chemical drug (drugs with known active ingredients approved for a new indication) to the treatment of common COVID-19 in adults in July 2022. Pursuant to the approval, we could commence commercial sales of azvudine for the COVID-19 indication and shall (i) conduct pharmacodynamic studies of azvudine against mutant variants of the SARS-CoV-2 virus; (ii) actively progress

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ongoing clinical trials of azvudine and submit trial reports upon completion; (iii) continue to collect efficacy and safety clinical data post-approval; and (iv) submit the required materials within three years of approval.

- In August 2024 and January 2025, we communicated with CDE for regular approval of azvudine for treatment of COVID-19.
- In July 2025, we submitted an application for a conversion of the conditional approval to a regular approval after completion of all required R&D work, and we expect to obtain the regular approval in the first half of 2026.

Russia

We authorized Beijing Union to carry out registration applications, clinical trials and application of azvudine for treating COVID-19 in Russia. See “—Our Technology Transfer Arrangements and Collaborations—Beijing Union Collaboration Agreements in Russia and Ukraine” for more details.

- In November 2020, Beijing Union submitted an IND application to the Russian MoH. In January 2021, the Russian MoH granted permission for the Phase III clinical trial of azvudine for treatment of COVID-19 in Russia.
- In February 2023, Beijing Union obtained the marketing authorization of azvudine for the treatment of COVID-19 in Russia from Russian MoH.

Brazil

We authorized Beijing Union and an Independent Third Party agent to carry out registration applications, clinical trials and application of azvudine for treating COVID-19 in Brazil. See “—Our Technology Transfer Arrangements and Collaborations—Tripartite Collaboration Agreements in Brazil and Other Regions of South America” for more details. In November 2020, an affiliate of the agent, who is also an Independent Third Party, submitted an IND application to the ANVISA. In March 2021, the ANVISA granted approval for the Phase III clinical trial for azvudine for treatment of COVID-19 in Brazil. As of the Latest Practicable Date, the Phase III clinical trial for azvudine in Brazil had been completed.

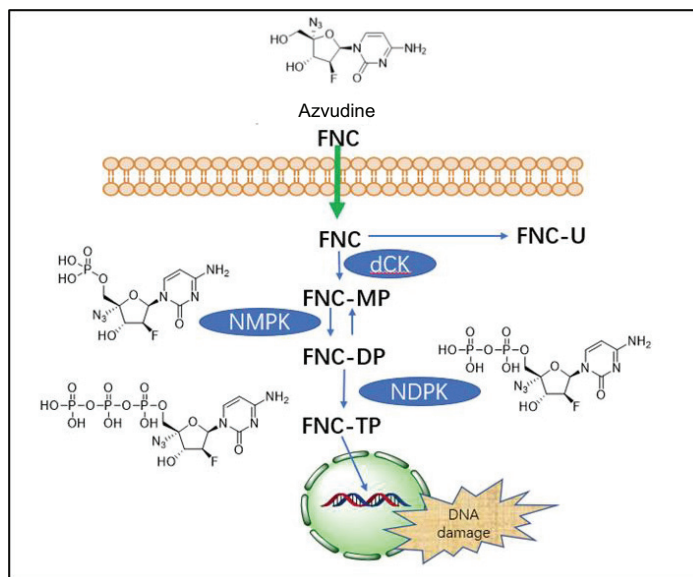
Other than the above, we have not had any material communications with the NMPA, the ANVISA or the Russian MoH for azvudine for treatment of COVID-19. As of the Latest Practicable Date, no material adverse change had occurred with respect to the review or approval process of azvudine for the treatment of COVID-19 in China, Russia or Brazil.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET AZVUDINE FOR THE TREATMENT OF COVID-19 SUCCESSFULLY.

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Blood Cancer

We are also developing our Core Product, azvudine, for the treatment of myeloma, lymphoma and acute leukemia. Azvudine has a dual anti-tumor mechanism, *i.e.*, it can not only inhibit the DNA synthesis of tumor cells, but also improve immunity through immune regulation to exert further anti-tumor effects. As a nucleoside analogue, azvudine can suppress the growth and proliferation of cancer cells by penetrating the synthesized nucleic acid chain and causing chain termination. The chart below illustrates the mechanism of action of azvudine for treating blood cancers:



Market Opportunities and Competition

Blood cancers include lymphoma, multiple myeloma and leukemia. Leukemia can be further categorized into acute lymphocytic leukemia (ALL), acute myeloid leukemia (AML), chronic lymphocytic leukemia (CLL) and chronic myeloid leukemia (CML). New cases of major types of blood cancer (including lymphoma, multiple myeloma, and leukemia) in China reached 0.20 million in 2024. It is estimated to reach 0.23 million in 2030, with a CAGR of 1.7% from 2024 to 2030. China's blood cancer drug market has reached US\$8.6 billion in 2024, and is expected to reach US\$24.1 billion in 2030, representing a CAGR of 14.0%.

Currently, chemotherapy drugs are the standard treatment for blood cancer patients in China. Nucleoside analogues, which serve as effective chemotherapeutic drugs, suppress the growth and proliferation of cancer cells by penetrating the synthesized nucleic acid chain and causing chain termination. As of the Latest Practicable Date, there had been four NMPA-approved nucleoside analogue ingredients recommended by Chinese Society of Clinical Oncology (CSCO) for treatment of each of lymphoma and acute leukemia. However, as of the Latest Practicable Date, CSCO had not specifically recommended any nucleoside analogue ingredient for treatment of multiple myeloma.

We believe that azvudine has the following potential advantages as compared to other blood cancer drugs:

Improved patient compliance. Azvudine (5 mg) can be an effective treatment through daily oral administration, while most of the existing nucleoside chemotherapy drugs for treating hematological diseases are administered intravenously.

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Good safety profile. Azvudine has demonstrated a good safety profile in our clinical trials for the HIV and COVID-19 indications. Preclinical *in vitro* studies have shown that azvudine could inhibit cell proliferation but did not have cytotoxic effect on healthy human PBMC and T cells in a six-hour treatment. Additionally, azvudine was well tolerated and achieved better efficacy in suppressing tumor growth than cytarabine at a much lower dosage level of 2 mg/kg as compared to cytarabine of 75 mg/kg.

Enhanced immunity. Azvudine has also demonstrated its potential to improve patients' immunity in multiple studies. In contrast, other nucleoside chemotherapy drugs have demonstrated severe bone marrow suppression reactions in clinical applications, indicating their immunosuppressive effects.

High potency. Azvudine has demonstrated potent activity against various blood cancer cell lines. In studies conducted in Molt 4 and Daudi cell lines, azvudine showed stronger inhibitory activity than cytarabine, an FDA-approved nucleoside-based medication for blood cancer. In terms of cancer progression, studies have also shown azvudine to inhibit adhesion, migration and invasion of tumor cells in a dose-dependent manner for Raji and JeKo-1, two human aggressive non-Hodgkin lymphoma cell lines.

We have completed preclinical studies of azvudine as a treatment of myeloma, lymphoma and acute leukemia. Our *in vitro* and *in vivo* studies have demonstrated the effectiveness of azvudine against blood cancer. Azvudine demonstrated stable, dose-dependent antitumor activity with favorable tolerability and no drug-related deaths across multiple hematologic malignancy models. We obtained an IND approval from the NMPA for the clinical trials of azvudine in patients with advanced solid tumors in September 2024, and initiated a Phase I clinical trial in January 2025 and completed the Phase I clinical trial in June 2025. See “—Azvudine + anti-PD-1—Summary of Clinical Results—Phase I Clinical Trial of Azvudine in Patients with Advanced Solid Tumors” for details of trial results. Based on the data collected from the Phase I trial, we submitted the IND application for the Phase IIa clinical trial for the treatment of blood cancers, received acceptance notification in September 2025, and obtained the IND approval in December 2025. We expect to kick off Phase IIa clinical trial in 2026 and complete this trial in 2027. We expect to initiate a Phase IIb clinical trial based on the results of the Phase IIa study.

Design of the Phase IIa Clinical Trial

The Phase IIa clinical trial is a single-arm, open-label clinical study designed to evaluate the safety, PK characteristics, and preliminary efficacy of azvudine tablets in patients with blood cancers. We plan to include two dose groups, i.e. 6 mg and 9 mg, administered orally once daily. We expect to enroll 12 to 20 subjects in this Phase IIa trial, and each dose group will enroll 6 to 10 subjects. Qualified subjects will be enrolled first in the 6 mg dose group, and the trial of 9 mg dose group will commence after the trial of the 6 mg dose group completes. One treatment cycle lasts for 21 days, until one of the following occurs: disease progression, death, intolerable toxicity, initiation of other anti-tumor therapy, withdrawal of informed consent, loss to follow-up, or other reasons for discontinuation, whichever occurs first.

Based on the safety, PK, and efficacy data from the two dose groups, the investigator and the sponsor may jointly decide whether to continue exploring additional higher dose groups. During the study, we will evaluate the safety of the use of azvudine in subjects, and collect data of adverse events and combination administration. During the adverse event reporting period, investigators should follow up on each adverse event until the event is resolved, the subject's condition stabilizes, a reasonable explanation is obtained, the subject is lost to follow-up, dies, or the subject withdraws consent.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET AZVUDINE AS TREATMENTS FOR MULTIPLE MYELOMA, LYMPHOMA AND ACUTE LEUKEMIA SUCCESSFULLY.

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Immunological Non-Responders (INRs) in HIV-infected Patients

We are also developing azvudine for the treatment of INRs—HIV-infected patients who have received ART for more than four years, maintained plasma viral load below the detection limit (i.e. <50 copies/mL) for over three years, yet continue to exhibit CD4⁺ T-cell counts persistently below 350 cells/μL, after excluding other causes of chronic CD4⁺ T-cell depletion. We have jointly applied with Peking Union Medical College Hospital of the Chinese Academy of Medical Sciences (中國醫學科學院北京協和醫院) for the R&D of such indication to be designated as a National Major Science and Technology Project of 2025 (2025年國家科技重大專項), and got approved by the Ministry of Science and Technology of the PRC.

Market Opportunity and Competition

INRs are estimated to occur in approximately 10% to 40% of treated HIV patients. Compared with immunological responders, INRs face significantly elevated risks of opportunistic infections, malignancies, non-AIDS-defining events, and mortality, highlighting a persistent unmet medical need despite effective virological control. Frost & Sullivan has advised that as of the Latest Practicable Date, no specifically indicated therapy had been globally approved for the treatment of INRs in HIV-infected patients. According to Frost & Sullivan, the global prevalence of INRs in HIV-infected patients grew from 13.7 million in 2020 to 14.8 million in 2025, and is expected to grow to 15.5 million in 2030. In China, such number increased from 424.5 thousand in 2020 to 462.5 thousand in 2025, and is projected to reach 528.2 thousand in 2030. According to the same source, the market size of HIV drugs for INRs in China is expected to reach RMB2.3 billion in 2028 and further grow to RMB2.4 billion by 2030 and RMB2.5 billion by 2035. Globally, the market size of HIV drugs for INRs is projected to reach US\$22.8 billion in 2028, and further increase to US\$25.7 billion by 2030 and US\$36.3 billion by 2035.

Summary of Clinical Trial and Near-term Plans

A single-center, single-arm exploratory investigator-initiated trial (“IIT”) was conducted in China to evaluate the efficacy of azvudine for the treatment of INRs in HIV-infected patients. 24 participants were enrolled and switched to an azvudine-based triple antiretroviral regimen for 48 weeks, in which lamivudine in their prior ART was replaced with 3 mg of azvudine once daily. Matched datasets were available for 24, 24, 23, and 21 patients at the 3-, 6-, 9, and 12-month follow-up visits, respectively. Absolute CD4⁺ T-cell counts increased significantly from a baseline of 258.3 ± 61.5 cells/μL to 337.9 ± 119.2 cells/μL, 364.7 ± 138.7 cells/μL, 387.0 ± 185.5 cells/μL, and 358.7 ± 112.0 cells/μL at the respective time points, corresponding to mean increases of 79.7 ± 106.4 cells/μL (Pairing t p=0.0013), 106.4 ± 121.9 cells/μL (Pairing t p=0.0003), 124.3 ± 174.1 cells/μL (Pairing t p=0.0024), and 89.0 ± 109.0 cells/μL (Pairing t p=0.0013). The CD4/CD8 ratio showed a sustained, statistically significant improvement, rising from 0.522 ± 0.275 at baseline to 0.679 ± 0.310 at month 12 (Pairing t p=0.0005), while CD8⁺ T-cell counts remained stable without clinically meaningful changes. These findings demonstrate that the azvudine-based regimens have the potential to effectively elevate CD4⁺ T-cell counts, restore CD4/CD8 immune balance, and promote immune reconstitution in HIV-infected INRs, supporting its promising clinical utility.

We expect to submit an application for the pivotal trial for the treatment of INRs in HIV-infected patients in China in the second half of 2026, and submit an IND application for Phase I clinical trial of the same therapy in the US in 2027. To maximize our likelihood to obtain the IND approval in the US, we plan to submit the clinical results generated from preclinical studies and clinical trials conducted in China, including the preclinical studies, Phase I, Phase II and Phase III clinical trials of azvudine, and the IIT in evaluating the efficacy of azvudine for the treatment of INRs in HIV-infected patients.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET AZVUDINE AS TREATMENT FOR INRs IN HIV-INFECTED PATIENTS SUCCESSFULLY.

Azvudine Combination Therapies for Cancer Treatment

Malignant tumor is a major disease that threatens the well-being and life of human beings. The development of targeted therapies have shifted the treatment paradigm for many cancer types, leading to a fast expansion of the oncology market. See “Industry Overview — The Oncology Drug

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Market — Global and China’s Oncology Drug Market” for details. As a nucleoside-based drug with dual mechanism, azvudine has good safety and is also expected to become a safe antitumor therapeutic drug. Azvudine can specifically and highly selectively bind into the tumor fine DNA, so that it can not complete the replication, and thus achieving a highly effective anti-tumor effect. Azvudine, at the same time, binds very little to the DNA of normal cells. Since nucleoside drugs have a different mechanism of action than non-nucleoside chemotherapeutic drugs and various targeted drugs, combination therapy with azvudine and any non-nucleoside chemotherapeutic drug or targeted drug may have a synergistic effect. To grasp the market opportunities and leverage azvudine’s dual anti-tumor mechanism, we have been developing azvudine combination therapy and other drug candidates for the treatment of various types of solid tumor including NSCLC, liver cancer, colorectum cancer, and expanding the indication treated by azvudine into blood cancer.

Azvudine + anti-PD-1

To further investigate the therapeutic potential of azvudine for the treatment of cancers, we are developing the combination therapy of azvudine and anti-PD-1 for the treatment of liver cancer and colorectal cancer. We have entered into a collaboration agreement with Innovent Biologics (Suzhou) Co., Ltd. (“**Innovent**”), a principal subsidiary of Innovent Biologics, Inc., a company listed on the Main Board of the Stock Exchange (01801.HK), under which Innovent has agreed to supply for nil consideration a sufficient quantity of SINTILIMAB, a commercialized anti-PD-1 agent owned by Innovent, for the Phase I clinical trial of azvudine + anti-PD-1 combination therapy for the treatment of cancer indications in accordance with the research and development plan approved by both parties. Sintilimab will be the exclusively designated PD-1 agent in our future standard-of-care treatment regimens. As the sponsor, we shall be responsible of conducting the clinical trial, while Innovent shall be granted access to the Phase I clinical data. See “—Our Technology Transfer Arrangements and Collaborations—Collaboration Agreement with Innovent” for details.

Market Opportunities and Competition

In 2024, there was approximately 2.0 million new cases of colorectal cancer worldwide, ranking third among all malignant tumors; there were 0.5 million new cases in China, ranking second among all malignant tumors. In 2024, there were approximately 0.91 million new cases of liver cancer worldwide, ranking sixth among all malignant tumors.

In recent years, immunotherapy based on immune checkpoint inhibitors (ICI) such as programmed cell death receptor-1 (PD-1) or programmed cell death ligand-1 (PD-L1) has developed rapidly, significantly improving the prognosis of many patients with advanced malignant tumors such as non-small cell lung cancer, liver cancer, and colorectal cancer. At present, as most patients still do not respond to PD-1/PD-L1 blockade, the mechanism has not yet been fully clarified. Its efficacy is limited by tumor immunogenicity and is poorly effective in patients with “cold tumors,” a problem particularly prominent in the treatment of colorectal cancer. Currently, PD-1 inhibitors only demonstrate limited efficacy in patients with microsatellite instability (MSI-H), which accounts for approximately 5% of colorectal cancer patients. Furthermore, the number of drugs approved for this indication is limited, and the overall benefit still has room for improvement. The vast majority of patients with microsatellite stable (MSS) colorectal cancer are generally insensitive to PD-1 inhibitor treatment, resulting in minimal clinical efficacy, creating a huge unmet treatment need. Therefore, the development of new anti-tumor drugs with both anti-tumor activity and the ability to regulate the tumor microenvironment is of great significance for the treatment of tumors.

Mechanism of Action and Advantages of our Drug Candidate

PD-1 is a type of receptor expressed on the surface of immune cells, including T cells. Cancer cells can upregulate the expression of PD-L1, which binds to PD-1 on T cells, thereby inhibiting the proliferation and activation of CD4⁺ T cells and CD8⁺ T cells and suppressing T cell responses to cancer cells. PD-1 inhibitors block the interaction between PD-1 and PD-L1 and restores T cell activity, leading to enhanced recognition and remission of cancer cells. Azvudine can also be used as an immunomodulator, effectively restoring and enhancing the anti-tumor killing function of T cells. By reshaping the tumor immune microenvironment, it transforms “cold tumors” with dormant immune responses into “hot tumors” with active immune cell infiltration, thereby exerting an

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antitumor effect. The tumor-suppressive effect of this mechanism is related to the expression of MDSCs in the tumor microenvironment, and the effect is better in solid tumors with more MDSC infiltration, such as liver cancer, colorectal cancer and NSCLC. During November 2019 to April 2020, we conducted the preclinical study of azvudine in the anti-tumor field, and continued preclinical studies of azvudine in such field during June 2022 to June 2023. In our preclinical animal studies described below, we verified the aforementioned mechanism. We believe the combination therapy of azvudine and anti-PD-1 has the potential to lead to stronger effect in the treatment of liver cancer and colorectal cancer due to the complementary mechanisms of action.

Our preclinical study in syngeneic models of CT26 colorectal cancer cell line, the combination therapy of azvudine (1 mg/kg QD) and PD-1 inhibitors (10 mg/kg twice weekly) significantly inhibited tumor growth after 4-week treatment as compared to the untreated control group and resulted in an increased TGI rate of 95.0% at day 21, as compared to the TGI rate of 83.0% in the azvudine monotherapy group of the same dose level and 39.0% in the anti-PD-1 monotherapy group of the same dose level. Furthermore, 70% of complete response (CR) was observed on day 27 in the combination therapy group and tumor remission continued after treatment was discontinued and a 100% tumor remission was observed on day 39. In addition, in the re-challenge study, there was no sign of recurrence, demonstrated that long-time immunologic memory and rejection to CT26 tumor cells were generated in the tested mice after four-week treatment of azvudine + anti-PD-1.

Our preclinical study in syngeneic models of H22 liver cancer cell line has demonstrated that the combination therapy of azvudine (0.5 mg/kg once a day) and PD-1 inhibitors (10 mg/kg twice weekly) significantly inhibited tumor growth after 4-week treatment as compared to the control group and resulted in an elevated TGI rate of 90.4% at day 20, as compared to the TGI rate of 66.8% in the azvudine monotherapy group of the same dose level and 79.6% in the anti-PD-1 monotherapy group of the same dose level.

In addition, several IITs were conducted to evaluate the potential of azvudine for the treatment of tumor indications.

- From September 2023 to March 2024, we conducted an investigator-initiated open-label clinical trial (Trial no. FNC23003) of azvudine (4 mg) to evaluate its efficacy and safety for the treatment of various late-stage solid tumors, including, among others, NSCLC, liver cancer and colorectal cancer. A total of 21 patients (including 6 with liver cancer, 5 with NSCLC and 4 with colorectal cancer) were enrolled, among which 11 patients had previously undergone anti-PD-1/PD-L1 treatment. Imaging evaluation showed that patients with past PD-1/PD-L1 immunotherapy experienced more tumor shrinkage than patients without past PD-1/PD-L1 immunotherapy.
- In April 2024, we obtained the approval from the ethics committee from a Grade 3A general hospital in Henan Province to conduct an investigator-initiated clinical trial (Trial no. FNC-IIT-C003) to evaluate the safety and efficacy of azvudine (5mg) in advanced solid tumors. This trial was ongoing as of the Latest Practicable Date.
- In May 2024, we initiated an investigator-initiated clinical trial (Trial no. FNC-IIT-C001) to evaluate the safety, tolerance and preliminary anti-tumor efficacy of azvudine in advanced solid tumors in a Grade 3A general hospital in Shanghai. This trial was ongoing as of the Latest Practicable Date.

Summary of Clinical Results

Phase I Clinical Trial of Azvudine in Patients with Advanced Solid Tumors

The Phase I clinical trial was a single-arm, multi-center, open-label clinical study for subjects with advanced solid tumors. The primary objective was to evaluate the safety and tolerability of azvudine tablets in patients with advanced solid tumors, explore DLTs, MTD and determine the RDE. The secondary objective is to evaluate the PK characteristics, anti-tumor efficacy, and impact on quality of life of azvudine tablets in patients with advanced solid tumors. The exploratory

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objective is to investigate the expression level of PD-L1 in tumor tissue and its correlation with efficacy; to investigate changes in the tumor microenvironment; to assess changes in myeloid-derived suppressor cells (MDSCs), lymphocyte typing (CD4⁺ T cells, CD8⁺ T cells, regulatory T cells, etc., and cytokines (interferons, interleukins, etc.) in whole blood before and after administration, and their correlation with efficacy.

We prepared and submitted the IND application without involving any other third parties, and obtained the IND approval from the NMPA for the clinical trials of azvudine in patients with advanced solid tumors in September 2024. We initiated Phase I trial in January 2025 and completed this trial in June 2025. Nine patients were enrolled in the Phase I clinical trial. The completed clinical trial has met its primary and secondary endpoints, and there was no deviation from the clinical trial protocol.

Trial Design. There would be three dose groups/cohorts: low (4mg), medium (6mg), and high (8mg), with a planned enrollment of 3 to 6 subjects in each dose group, and a total of 12 to 18 subjects for the entire Phase I trial. Qualified subjects would be assigned to the three dose groups in order of enrollment. They will receive a single dose on the first day (D1), be observed for four days, and then receive continuous dosing daily (QD) starting on the fifth day (D5) for 21 consecutive days (D5 to D25). We would adopt the “3+3 dose-escalation design”, with the safety monitoring committee making the decision on dose escalation. The study would commence in the next dose cohort only after all subjects in the current dose cohort have completed the DLT assessment (D1-D25). After each subject completes the DLT assessment and the investigator determines that the benefits of continued treatment outweigh the risks, the subject may continue to receive azvudine tablets at the original dose until disease progression, death, unacceptable toxicity, initiation of other anticancer therapy, withdrawal of informed consent, loss to follow-up, or discontinuation for other reasons, whichever occurs first. If the MTD of azvudine tablets cannot be determined at the maximum dose, the safety monitoring committee will discuss whether to explore a higher dose based on the existing safety and preliminary efficacy data.

Trial Results. Although azvudine tablets did not meet the response criteria according to RECIST (Response Evaluation Criteria in Solid Tumors) guidelines (version 1.1) imaging assessment in patients with advanced solid tumors at the end of treatment, disease progression was controlled in these patients, and some patients showed a trend of tumor shrinkage. Furthermore, azvudine tablets had a favorable safety profile, providing a treatment option for patients with advanced solid tumors. A summary of the major safety and efficacy data are set forth as follows:

Safety. In this study, nine subjects met the DLT observation criteria. No DLT events were observed during the DLT observation period. During the trial, one subject (11.1%) died from a lung malignancy, which the investigators considered unrelated to azvudine. One subject (11.1%) experienced a serious AE, pneumonia, in the 4 mg dose group, which was unrelated to azvudine. All subjects experienced at least one TEAE during treatment. Common TEAEs (≥ 2 cases) included: metabolic and nutritional disorders (55.6%), blood and lymphatic system disorders (33.3%), respiratory, thoracic, and mediastinal disorders (22.2%), and systemic disorders and administration site reactions (22.2%). No subjects experienced Grade 3 TEAEs. Eight subjects experienced TRAEs (≥ 2 cases). Common TRAEs included hypoalbuminemia (33.3%), anemia (33.3%), increased alkaline phosphatase (22.2%), and increased alanine aminotransferase (22.2%). No subjects in this trial experienced death, drug discontinuation, dose modification, or drug interruption due to TEAEs. It is therefore concluded that azvudine tablets have demonstrated a favorable safety profile for the treatment of advanced solid tumors, and no new safety risks have been identified compared to previous clinical trial results.

Efficacy. The median age of subjects enrolled in this trial was 58 years. The majority (66.7%) were male. All subjects were stage IV according to the American Joint Committee on Cancer Staging Manual (8th edition). The majority (88.9%) had metastatic disease at enrollment, with the most common metastatic sites being lymph node metastases (88.9%), followed by lung metastases (55.6%), adrenal metastases (33.3%), brain metastases (22.2%), and pleural metastases. More than half of the participants (66.7%) had received three prior lines of therapy, and the median duration of prior anti-PD-1/anti-PD-L1 therapy was 13.207 months. The FAS consisted of nine subjects. Based on the FAS analysis set: The DCR was 33.3% (95% CI: 7.49%, 70.07%), the overall median PFS was 1.5 months (95% CI: 1.45, NA), the 3-month progression-free survival rate was 31.3% (95% CI: 4.78%, 64.08%), the overall median overall survival was not evaluable (95% CI: 1.91, NA), and the 3-month overall survival rate was 88.9% (95% CI: 43.30%, 98.36%).

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As of the data analysis cutoff date (May 24, 2025), three subjects in the 8 mg dose group had not yet reached their first tumor assessment and had no post-baseline tumor assessment data. One subject in the 6 mg dose group had no post-baseline tumor assessment data and was not included in the PPS analysis set. This PPS analysis set efficacy analysis focused solely on the 3 subjects in the 4 mg dose group and the remaining 2 subjects in the 6 mg dose group. According to investigator assessment, no subject achieved a complete response (CR) or partial response (PR), but one subject in the 6 mg dose group achieved the best response, which was a reduction in SD. The DCR for the 4 mg dose group was 95% CI 0.84%, while the DCR for the 6 mg dose group was 95% CI 1.26% to 98.74%, and the overall DCR was 95% CI 5.27% to 85.34%. The median PFS for the 4 mg dose group was 1.4 months (95% CI 1.45 to NA), the median PFS for the 6 mg dose group was 1.9 months (95% CI NA to NA), and the overall median PFS was 1.9 months (95% CI 1.45 to NA).

Material Communications and Next Steps

We obtained the IND approval from the NMPA for the clinical trials of azvudine in patients with advanced solid tumors in September 2024. We initiated Phase I trial in January 2025 and completed this trial in June 2025. The data of Phase I trial will be used to support the combination therapy of azvudine + anti-PD-1 for the treatment of liver cancer and colorectal cancer.

We submitted IND applications for the combination therapy of azvudine + anti-PD-1 for the treatment of liver cancer and colorectal cancer in December 2025, and obtained the IND approvals in February 2026. In addition, we commenced a single-arm, single-center and open-label investigator-initiated clinical study in patients with advanced solid tumors in China to evaluate the safety, tolerability and preliminary anti-tumor potency of azvudine in August 2024. We are conducting a dose escalation (3 mg, 4 mg, 5 mg, 6 mg, 7 mg and 8 mg) phase and a dose expansion phase for this trial, and plan to enroll 16-60 patients and 30-120 patients for each phase, respectively. As part of our global expansion strategy, we also plan to apply for IND for the combination therapy of azvudine + anti-PD-1 in jurisdictions overseas following its IND approval in China.

As communicated with the Sixth Supervision Bureau of Henan Medical Products Administration on May 13, 2024, the Sixth Supervision Bureau of Henan Medical Products Administration confirmed that a combination therapy of a new drug (in this instance, azvudine) with an existing marketed drug (in this instance, PD-1 inhibitors) will be regulated as the same product as such new drug for regulatory purposes and shall be evaluated through necessary clinical trials as required for indication expansion of the new drug. Based on this confirmation, we believe that the combination therapy of azvudine + anti-PD-1 is regarded as an indication expansion of azvudine.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET AZVUDINE + ANTI-PD-1 AS TREATMENT FOR LIVER CANCER OR COLORECTAL CANCER SUCCESSFULLY.

Azvudine + Dosimertinib

As a nucleoside analogue, azvudine can induce tumor cells to release damage-associated molecular patterns (DAMPs), which interact with immune cells and could enhance APCs' ability of antigen presenting to improve the ability of T cells to kill and damage tumor cells. In addition, azvudine reduces myeloid-derived suppressor cells in the tumor microenvironment and promotes the infiltration and expansion of natural killer (NK) cells and T cells, thereby augmenting the immune cell-mediated cytotoxicity against tumor cells. We believe azvudine and dosimertinib's complementary mechanisms have the potential to lead to synergistic effect in the treatment of NSCLC. In our preclinical studies in CDX models of the NCI-H1975 NSCLC cell line, the combination therapy of azvudine (1 mg/kg QD) and dosimertinib (2.5 mg/kg QD) resulted in an elevated TGI rate of 92.82%, as compared to the TGI rate of 87.50% in the dosimertinib monotherapy group of the same dose level. We have completed the preclinical studies and obtained an IND approval for azvudine + dosimertinib for the treatment of NSCLC in September 2025 based on results of the Phase I clinical trial of dosimertinib for the treatment of NSCLC completed in May 2025 and the results of the Phase I clinical trial of azvudine in patients with advanced solid tumors completed in June 2025. We initiated the Phase I/IIa clinical trial in November 2025.

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Summary of the Ongoing Phase I/IIa Clinical Trial

This Phase I/IIa clinical trial is a single-arm, open-label study to evaluate the safety and efficacy of azvudine combined with dosimertinib in patients with locally advanced or metastatic NSCLC harboring EGFR mutations. This study consists of a Phase I dose-escalation phase and a Phase IIa dose-expansion phase. The prespecified doses of azvudine in the dose-escalation phase are 6 mg and 8 mg daily; the prespecified doses of dosimertinib are 80 mg, 160 mg, and 200 mg daily. The dose-escalation phase is expected to enroll 13-30 subjects.

Phase I clinical trial. The primary endpoints of the Phase I clinical trial are the incidence and severity of DLTs and AEs, and the vital signs, physical examination, laboratory tests (blood count, blood biochemistry, coagulation function, and urinalysis), and other tests (echocardiogram, etc.). The secondary endpoints of the Phase I clinical trial are efficacy indicators including ORR, DCR, PFS, DOR and OS; and PK parameters including time to peak concentration (T_{max}), half-life ($t_{1/2}$), area under the drug concentration-time curve from time 0 to the last measurable concentration (AUC_{0-t}), area under the drug concentration-time curve from time 0 to the estimated infinity (AUC_{inf}), area under the drug concentration-time curve from time 0 to the dosing interval (AUC_{τ}), clearance (CL), apparent volume of distribution (V_z), steady-state trough concentration (C_{trough}), steady-state peak concentration ($C_{max,ss}$), accumulation ratio (R_{ac}), etc. The exploratory endpoints of the Phase I clinical trial are (i) to explore the correlation between whole blood bone marrow-derived suppressor cells (MDSCs), lymphocyte typing ($CD4^+$ T, $CD8^+$ T, regulatory T cells (Tregs), and cytokines (interferons (IFNs) and interleukins (ILs)) and treatment efficacy, and (ii) to explore the correlation between gene mutations in plasma free ctDNA and/or tumor tissue and therapeutic efficacy.

The Phase I trial consists of five dosing groups, being dosimertinib 80 mg + azvudine 6 mg, dosimertinib 160 mg + azvudine 6 mg, dosimertinib 160 mg + azvudine 8 mg, dosimertinib 200 mg + azvudine 6 mg and dosimertinib 200 mg + azvudine 8 mg. As of the Latest Practicable Date, we had enrolled one subject for the first dosing group, three subjects for the second dosing group, and three subjects for the third dosing group.

Both escalation cohorts in the dose-escalation phase adopted an accelerated titration “3+3” design. The DLT observation period was from Day 1 to Day 21. If the MTD cannot be determined after escalation to the highest dose, the investigator and the sponsor may jointly decide whether to continue dose escalation (and determine the specific dose) or to discontinue dose escalation.

After the DLT observation period for all subjects in each dose group has concluded, the investigator and the sponsor will discuss and determine dose escalation and other decisions based on the previous observations. The highest dose of azvudine to be escalated should refer to the highest dose of azvudine previously escalated as a single agent. The sponsor and investigator will discuss and decide whether to adjust the escalation ratio and dose setting based on preliminary safety, PK, and efficacy results of azvudine obtained during the study.

During the dose-escalation study, if none of the three subjects in a particular dose group experienced a DLT, the investigator, in consultation with the sponsor, may decide to enroll 10 to 20 subjects in that dose group based on further safety, PK, and efficacy observations. Priority will be given to patients with untreated brain or meningeal metastases. These subjects will undergo sparse PK blood sampling.

Phase IIa clinical trial. The primary endpoints of the Phase IIa clinical trial are efficacy indicators including ORR and intracranial objective response rate (only in the group with brain metastases), and safety indicators including AEs, vital signs, physical examination, laboratory tests (blood routine, blood biochemistry, coagulation function, and urine routine), and other tests (echocardiography, etc.). The secondary endpoints of the Phase IIa clinical trial are efficacy indicators including PFS, DOR, DCR, OS and intracranial progression-free survival (only in the group with brain metastases), and PK parameters including T_{max} , $t_{1/2}$, AUC_{0-t} , AUC_{inf} , AUC_{τ} , CL, V_z , C_{trough} , $C_{max,ss}$, R_{ac} , etc. The exploratory endpoints of the Phase IIa clinical trial are (i) to explore the correlation between MDSCs, lymphocyte typing ($CD4^+$ T, $CD8^+$ T, Treg), and cytokines (IFN and IL, etc.) in whole blood and efficacy, and (ii) to explore the correlation between gene mutations in plasma free ctDNA and/or tumor tissue and therapeutic efficacy.

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After the Phase I dose-escalation study is completed, the sponsor and investigators will determine the RP2D based on the safety, tolerability, PK, and efficacy information obtained, and then enter the dose expansion phase using the RP2D. The extension period is divided into two cohorts:

Cohort 1: Approximately 20 to 30 NSCLC patients with disease progression after prior treatment with third-generation EGFR-TKIs (were allowed to receive chemotherapy and/or first- or second-generation EGFR-TKIs).

Cohort 2: Approximately 20 to 30 NSCLC patients without prior treatment by EGFR-TKIs (were allowed to receive chemotherapy).

During the Phase I dose-escalation and Phase IIa dose-expansion studies, subjects will receive azvudine + dosimertinib, every 21 days as one cycle, until one of the following occurred: disease progression, intolerable toxicity, subject withdrawal, or the investigator determined that the subject no longer benefited from treatment, whichever occurs first.

During the study, subjects will undergo hematologic ctDNA and/or tumor tissue NGS genetic testing during the screening period, upon achieving PR/CR, and upon disease progression/treatment completion. Blood samples will be collected during the screening period, upon achieving PR/CR, and upon disease progression/treatment completion for exploratory immune function studies to explore the correlation between the tumor immune microenvironment and drug efficacy. This includes whole-blood analysis of MDSCs, lymphocyte typing (CD4⁺ T, CD8⁺ T, Treg), and cytokines such as IFN and IL.

During the study, the safety of the study drug will be evaluated, and AEs and concomitant medication use will be collected. During the AE reporting period, investigators should follow up on each adverse event until the event is resolved, the patient's condition stabilizes, a reasonable explanation is obtained, the patient is lost to follow-up, dies, or the subject withdraws consent.

During the study, investigators will conduct tumor assessments according to RECIST 1.1 criteria every 6 weeks (± 7 days) until disease progression, loss to follow-up, withdrawal of consent, death, or initiation of new anticancer therapy, whichever occurs first. Tumor assessment timing will not be affected by dose adjustments or interruptions. Patients with a PR/CR result at the initial assessment will require confirmation at least 4 weeks later.

During the study, blood samples will be collected for PK evaluation.

After the last dose is completed, all subjects will be followed up for survival every 12 weeks ± 7 days until death, loss to follow-up, withdrawal of consent, or the investigator/sponsor's decision to terminate the study, whichever occurs first.

Material Communications and Next Steps

We obtained an IND approval for azvudine + dosimertinib for the treatment of NSCLC in September 2025, and we initiated this Phase I/Phase IIa trial in November 2025.

As communicated with the Henan Medical Products Administration on April 17, 2025, the Sixth Supervision Bureau of Henan Medical Products Administration confirmed that a combination therapy of a new drug will be subject to the same regulatory oversight as such new drug. Based on this confirmation, we believe that the combination therapy of azvudine + dosimertinib is regarded as an indication expansion of azvudine.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET AZVUDINE + DOSIMERTINIB FOR THE TREATMENT OF NSCLC SUCCESSFULLY.

Azvudine + CTX

In addition to the azvudine monotherapy, we are also exploring the combination therapy of azvudine and chemotherapy drugs, which remain a widely adopted treatment option for various cancers, for the treatment of lymphoma. In our preclinical studies in PDX models (patient-derived

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xenograft models, where tumor cells from patients are implanted into immunodeficient mice) of the LY3148 lymphoma cell line, the combination of azvudine with CTX demonstrated great potential for the treatment of lymphoma. CTX is a type of alkylating agent that could prevent cell proliferation by cross-linking DNA strands and inhibiting DNA synthesis, and has been approved by the FDA and the NMPA for the treatment of various cancers, including lymphoma. The CTX agents used in our preclinical studies and planned clinical trials can be any commercialized CTX in the market, which we procure through CROs. In our preclinical studies, compared to the untreated control group, both the azvudine and the CTX monotherapy groups showed significantly inhibited tumor growth, with a TGI (tumor growth inhibition) rate of 84.46% and 81.29% after two weeks, respectively, at the dosage of 1mg/kg once a day (QD) and 30 mg/kg once a week (QW), respectively. The combination of azvudine and CTX showed encouraging effect, achieving 100% tumor remission in all models in the combination therapy group after two weeks at the same dose levels. In this group, during the post-treatment observation period (from day 14 to day 60), the tumors in two models remained without recurrence, and the median survival time was 54.5 days, increased by 289.3% compared to the untreated control group.

Taking into account the fact that the data from Phase I trial for the treatment of solid tumor can support later stage clinical trials for the treatment of blood cancers and the clinical trials for combination therapies, we submitted the IND application for the Phase II clinical trial of azvudine monotherapy for the treatment of blood cancers, received acceptance notification in September 2025 and obtained the IND approval in December 2025. We expect to submit an IND application for azvudine + CTX for the treatment of lymphoma in the second half of 2026. Upon approval, we intend to further explore the potential of the combination therapy in clinical trials, including investigating the viability of a combination regimen with reduced dosage of CTX to mitigate potential adverse effects and enhance the safety profile of the product.

As communicated with the Sixth Supervision Bureau of Henan Medical Products Administration on May 13, 2024, the Sixth Supervision Bureau of Henan Medical Products Administration confirmed that a combination therapy of a new drug (in this instance, azvudine) with an existing marketed drug (in this instance, CTX) will be regulated as the same product as such new drug for regulatory purposes and shall be evaluated through necessary clinical trials as required for indication expansion of the new drug. Based on this confirmation, we believe that the combination therapy of azvudine + CTX is regarded as an indication expansion of azvudine.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET AZVUDINE + CTX AS TREATMENTS FOR BLOOD CANCER SUCCESSFULLY.

All-Oral Long-Acting Composite Tablet

HIV is a highly mutating virus, and currently, no single drug can effectively prevent viral mutations. Once the virus mutates, treatment becomes significantly more difficult. Therefore, the “Chinese Guidelines for the Diagnosis and Treatment of HIV/AIDS (2024 Edition)” currently recommends the simultaneous use of at least two or three drugs with different mechanisms of action. The azvudine/CL-197 can realize combined action on three targets, thus the composite tablet is by itself a cocktail therapy for the treatment of HIV infection while being expected to reduce the risk of drug resistance based on the preclinical study data.

It is also worth noting that all currently available HIV treatments worldwide require daily administration. Even long-acting drugs like Albuvirtide which can be injected every two weeks still requires daily administration of two other oral medications in combination, which may impact the patients’ adherence.

In light of the proved long-acting effect of both azvudine and CL-197, we are therefore committed to developing a once-weekly oral composite tablet. We believe that this combination would also benefit from combined mechanisms of azvudine and CL-197 by mimicking endogenous pyrimidine and purine nucleotides. Particularly, we plan to develop an all-oral long-acting composite tablet based on this combination for the treatment of HIV infection, which we believe has the potential to be administered orally on a weekly basis with long-acting effects and strengthen patient adherence.

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We have completed the preclinical research on azvudine/CL-197 dual-drug long-acting oral treatment for HIV, focusing on the development of long-acting oral formulations. Besides, prior to the commencement of the clinical trial of the long-acting composite tablet, we expect to complete the Phase II clinical study on the safety, tolerability, PK, and PD of CL-197 capsules in HIV-1 treatment-naïve patients. Such trial is designed to be administered once weekly, with the aim of verifying the long-acting mechanism. Clinical trial of the composite tablet is expected to commence in the second half of 2026.

As communicated with the Henan Medical Products Administration on April 17, 2025, the Sixth Supervision Bureau of Henan Medical Products Administration confirmed that a combination therapy of a new drug will be subject to the same regulatory oversight as such new drug. Based on this confirmation, we believe that the combination therapy of azvudine/CL-197 is regarded as an indication expansion of azvudine.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ALL-ORAL LONG-ACTING COMPOSITE TABLET SUCCESSFULLY.

CL-197—Our Core Product

In addition to azvudine, we are developing CL-197, another new NRTI that can inhibit reverse transcription by mimicking endogenous purine nucleotides, and has potential long-term effects in the treatment of HIV infection. Pharmacokinetic studies in an oral gavage animal model showed that the half-life of CL-197 in PBMC was about 168 hours, confirming its potential for long-term efficacy and possibly improving medication compliance. CL-197 demonstrated promising results with respect to safety, tolerability and PK characteristics in its Phase I clinical trial.

We completed the IND-enabling preclinical studies for CL-197 in December 2021 and submitted an IND application for CL-197 in China in July 2022, which was approved by the NMPA in October 2022. We commenced the Phase I clinical trial for CL-197 in China in August 2023 and completed this trial in March 2025. We obtained the ethics committee approval for the Phase IIa clinical trial of CL-197 in September 2025. CDE reviewed the Phase IIa trial design in October 2025 and expressed no objection. We commenced the Phase IIa trial in November 2025, and expect to complete the Phase IIa trial and initiate Phase IIb trial in 2026.

Mechanism of Action

Similar to azvudine, CL-197 is a novel NRTI with antiviral activity on HIV. For details of a NRTI's mechanism of action, see “—Our Product Portfolio—Azvudine—HIV Infection—Mechanism of Action.”

Market Opportunity and Competition

The HIV drug market is growing globally and in China with cART becoming the global standard of care attributable to its improved efficacy and safety profile. See “Industry Overview—Antiviral Drug Market—The HIV Drug Market” in this document for a detailed discussion of the global and China HIV drug market. With prolonged virologic suppression and improved clinical outcomes, HIV patients now have a longer survival period and are likely exposed to antiretroviral agents for decades. Therefore, the current R&D of HIV drugs focuses on improving drug safety, efficacy, resistance and treatment simplification (such as a single-tablet and/or less frequent dosing regimen) for improved compliance. See “Industry Overview—Antiviral Drug Market—The HIV Drug Market—Competitive Landscape of HIV Drugs” for the competitive landscape of drug candidates for treatment of HIV infection in China.

We believe that CL-197 is in line with the global trend of developing next-generation HIV drugs with such features. Particularly, CL-197 will be administered orally and has the potential of being administered only once per week. Such relatively convenient drug regimen may also improve compliance and thus improve clinical outcomes.

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Summary of Ongoing Phase IIa Clinical Trial

We are conducting a Phase IIa clinical trial of azvudine for the treatment of HIV infection in adults to explore the efficacy of CL-197 capsules in treating treatment-naïve HIV-1 patients and to evaluate the safety, tolerability, PK characteristics, and drug exposure/drug ratio of a single capsule administration in treatment-naïve HIV-infected individuals. It is a single-center, single-arm, single-dose, open-label trial, which commenced in November 2025.

Trial Design. The primary objective of the clinical trial is to explore the efficacy of CL-197 capsules in treating HIV-naïve patients. The secondary objectives are to (i) evaluate the safety and tolerability of a single dose of CL-197 capsules in treatment-naïve HIV-1 infected, (ii) to evaluate the PK characteristics and drug exposure of a single dose of CL-197 capsules in treatment-naïve HIV-1 infected individuals, and (iii) to evaluate the change of immunological function (CD4⁺ T cell count) in treatment-naïve HIV-infected individuals after a single dose of CL-197 capsules.

There will be three dose groups, i.e. 10 mg, 30 mg, and 60 mg, each containing 8 participants. The clinical trial will be conducted in two parts:

- Part 1: A single-dose study at a dose of 30 mg will be conducted initially. Once all participants have left the study on day 13, the safety assessment team (principal investigator and sponsor representative) will decide whether to proceed with Part 2, making a decision to continue or discontinue the study. If the study is to continue, Part 2 will be conducted.
- Part 2: A single-dose study of the 60mg dose group will be conducted. After all subjects have completed their dosing, single-dose study in the 10mg dose group will be conducted.

Each part is divided into three phases: screening period (D-28~D-1), baseline period (D-3~D-1), and administration and sample collection period (D1~D13). After completing sampling after 288h (D13), subjects will be transferred to standardized anti-HIV treatment as soon as possible.

The primary endpoint is the change in the Log10 value of HIV-1 RNA from baseline on day 8. The secondary endpoints are (i) the correlation between CL-197 capsules and PK/PD, (ii) the change in HIV-1 RNA Log10 value on day 11 from baseline, (iii) the change in CD4⁺ T cell count on day 13 from baseline, (iv) incidence of AEs/SAEs, and (v) PK parameters of CL-197 capsules.

The safety parameters include: vital signs, physical examination, complete blood count, urinalysis, blood biochemistry, and blood pregnancy test (female subjects only). Researchers shall observe all subjects for any AEs that occur during the clinical trial and shall record such clinical characteristics, severity, time of occurrence, time of termination, treatment measures, and outcomes, and determine the correlation between the study drugs.

Non-compartmental model pharmacokinetic parameters shall be estimated and analyzed based on blood drug concentration data, and major PK parameters shall be calculated.

PD data shall be analyzed and evaluated, including the comparison of HIV-1 RNA Log10 values on days 11 and 8 from the baseline, the change in CD4⁺ T cell count on day 13 compared to baseline.

Safety analysis was performed using the Safety Analysis Set (SS). The incidence of adverse events/serious adverse events shall be analyzed. Clinical laboratory test values, vital signs, electrocardiograms, etc., are subject to corresponding descriptive statistical analysis according to the data type.

Summary of Phase I Clinical Trial

Trial design. The Phase I clinical trial was a single-center, randomized, double-blinded, placebo-controlled and single ascending-dose trial in China to evaluate the safety, tolerability and PK profile of CL-197 in healthy subjects after a single dose administration. The primary endpoints

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were the safety and tolerability parameters of CL-197. The secondary endpoints were the PK characteristics of CL-197. We enrolled a total of 44 subjects, who would be assigned to five groups with different dose levels (1 mg, 10 mg, 30 mg, 60 mg and 100 mg). We assigned 4 subjects to the 1 mg group and 10 subjects to each of the remaining groups (8 receiving CL-197 and 2 receiving placebo in these groups). Each subject would only receive one dose of either CL-197 or placebo at the designated dose level.

Trial status. The Phase I clinical trial was initiated in August 2023 and completed in March 2025 with a total of 44 subjects were enrolled. The completed clinical trial has met its primary and secondary endpoints, and there was no deviation from the clinical trial protocol.

Trial results. CL-197 demonstrated promising results with respect to safety, tolerability and PK characteristics in its Phase I clinical trial. Notably, a single dose of CL-197 capsule ranging from 1 to 100mg (the maximum dosage of this trial), was well tolerated with no dosage-related adverse events observed. In addition, clinical data from the Phase I clinical trial indicated that part of CL-197 distributed into peripheral blood mononuclear cells (PBMCs) following oral administrations. Once CL-197 was converted to its active form, CL-197-TP in PBMCs, its half-life is significantly extended compared to plasma, suggesting a long-acting mechanism.

Summary of Preclinical Studies

We completed the IND-enabling preclinical studies for CL-197 in December 2021. Results from a preclinical study to evaluate the pharmacodynamics of CL-197 showed that CL-197 could effectively inhibit replication of an HIV strain. Additionally, CL-197 has demonstrated its long-acting feature in pharmacokinetic studies in beagle models under oral gavage administration, which showed that it has a half-life of approximately 168 hours in PBMC. This study suggests that CL-197 has the potential to be administered weekly with long acting effects.

Material Communications and Near-term Plans

We, together with Henan Normal University (a public university in China) and Meitaibao, submitted an IND application for CL-197 in China in July 2022 and received the IND approval in October 2022. Pursuant to a framework agreement among the three parties entered into on April 6, 2022, the parties will be co-applicants for the NMPA registration of CL-197 but we shall independently perform all subsequent R&D work and remain the sole MAH of CL-197. Meitaibao and Henan Normal University are entitled to be named as co-sponsors in the IND application and clinical trials considering their contributions in the early drug discovery stage. Subject to the approval of the relevant authority, the sponsor of a clinical trial can be changed after the IND approval is obtained. We do not anticipate any obstacles for obtaining such approval from the NMPA.

We commenced the Phase I clinical trial for CL-197 in August 2023 and completed this trial in March 2025. We obtained the ethics committee approval for a Phase IIa clinical trial for CL-197 in September 2025. CDE reviewed the Phase IIa trial design in October 2025 and expressed no objection. We commenced the Phase IIa trial in November 2025, and expect to complete the Phase IIa trial and initiate Phase IIb trial in 2026. As part of our global expansion strategy, we also plan to apply for IND for CL-197 in jurisdictions overseas such as the United States.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CL-197 FOR THE TREATMENT OF HIV INFECTION SUCCESSFULLY.

Dosimertinib—Our Core Product

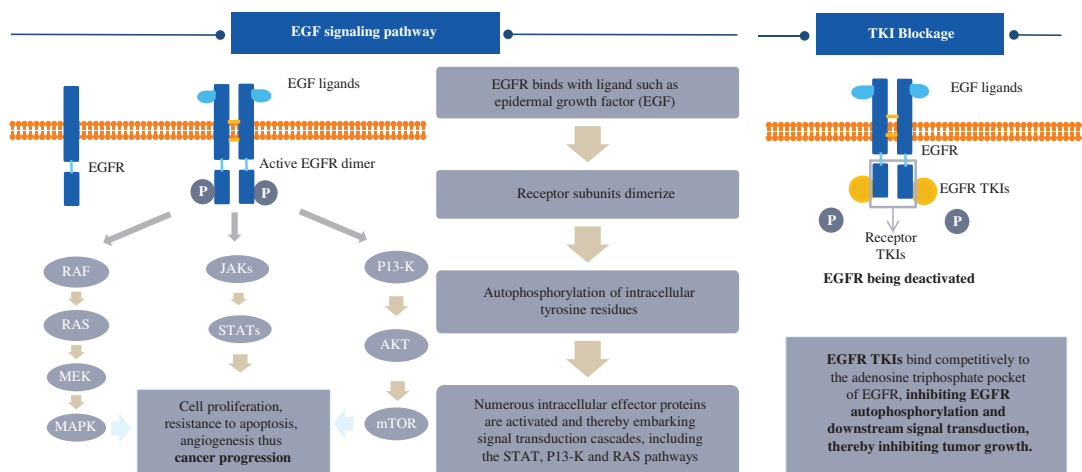
We are developing dosimertinib, our Core Product, a potent, selective and orally administered epidermal growth factor receptor (EGFR)-targeting drug candidate, for the treatment of advanced EGFR mutation-positive non-small cell lung cancer (NSCLC), one of the most prevalent types of lung cancer in China. Dosimertinib is designed to address the medical needs of advanced NSCLC patients harboring EGFR mutations that are resistant to previous generations of targeted drugs. Preclinical pharmacokinetic studies have shown that the levels dosimertinib are higher in lung and brain tissue than those of osimertinib, demonstrating dosimertinib has an advantage in the treatment of lung cancer and brain metastases.

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We, as the sole sponsor of the clinical trials of dosimertinib, are conducting a Phase I/Phase II clinical trial in China to investigate the safety and efficacy of dosimertinib. We completed the Phase I trial, being the dose escalation stage of the Phase I/Phase II trial, in May 2025. In the Phase I clinical trial, we enrolled 23 patients have observed an overall good safety profile and good dose-related efficacy. No DLTs were observed in the dosimertinib 20 mg, 40 mg, 80 mg, 160 mg, 200 mg or the 240 mg dose group. In addition, dosimertinib began to show efficacy from a dose of 20 mg, and the subjects in the 80 mg and above dose groups received more significant clinical benefits. The tumor assessments of three patients in the 240 mg dose group showed significant efficacy, with one patient assessed as SD with shrinkage and the disappearance of non-target lesions in the brain, and two patients assessed as PR.

Mechanism of Action

Similar to osimertinib, an FDA- and NMPA-approved treatment for NSCLC, dosimertinib is a third-generation EGFR tyrosine kinase inhibitor (EGFR-TKI). EGFR is a type of transmembrane protein that is involved in cell signaling pathways that control cell proliferation. When over-activated, EGFR could help the rapid growth and division of cancer cells. EGFR-TKIs block the activity of EGFR by blocking its intracellular kinase domain, therefore preventing its autophosphorylation, an essential process for EGFR to become an active molecule, and subsequent activation. In terms of molecular structure, dosimertinib is a “deuterated” version of osimertinib, where multiple hydrogen atoms are substituted with deuterium, a heavy stable isotope of hydrogen. Such substitution leads to positive impact on the pharmacokinetic, therapeutic and toxicological profiles of select compounds. The following picture demonstrates the mechanism of action of dosimertinib:



Source: Frost & Sullivan

Market Opportunity and Competition

Lung cancer is the malignant tumor with the highest incidence and mortality rate worldwide and in China. Among them, NSCLC is the most common type of primary lung cancer, accounting for about 85% of all lung cancers worldwide. China’s NSCLC incidence reached approximately 0.9 million in 2024. The incidence of NSCLC in China is expected to further increase to approximately 1.1 million by 2030.

There are significant unmet medical needs of NSCLC patients in China because of NSCLC’s poor survival rate, complexity of different disease subtypes and drug resistance. According to the United States National Comprehensive Cancer Network Guidelines, treatments of early-stage NSCLC is mainly surgery and radiotherapy. Meanwhile, targeted drugs, including EGFR-TKIs, are used for patients with advanced NSCLC. As of the Latest Practicable Date, there were 19 EGFR-TKIs approved for NSCLC treatment in China, among which 10 had been approved for first-line treatment for advanced EGFR mutation-positive NSCLC. See “Industry Overview—The Oncology Drug Market—The NSCLC Drug Market” in this document. The targeted therapies for NSCLC are usually mutation-specific and could become less effective toward newly emerged mutations. The first two generations of EGFR-TKIs typically target sensitive and moderately sensitive mutations of EGFR, but are not effective against EGFR T790M. Osimertinib is a third-generation EGFR-TKI, but its primary toxic metabolite, AZ5104, exhibits a reduced selectivity margin against wild-type EGFR, which leads to heightened concerns over its potential toxic effects.

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Dosimertinib is a drug candidate under development for the treatment of advanced EGFR mutation-positive NSCLC. We are evaluating its potential attributes based on available preclinical and clinical data. Dosimertinib has shown, in *in vitro* assays and animal studies, efficacy in anti-tumor activity, improved safety, and achieved higher exposure levels in lung and brain tissues, compared with osimertinib.

Summary of Clinical and Preclinical Results

Phase I/Phase II Clinical Trial

The Phase I/Phase II clinical trial is an open-label, dose escalation and dose expansion clinical study evaluating the safety, tolerance, pharmacokinetic characteristics and preliminary efficacy of oral administration of dosimertinib for treatment of patients with EGFR T790M mutation-positive locally advanced or metastatic NSCLC. We communicated with the NMPA in May 2019 regarding this trial. We obtained an IND approval for our Phase I/Phase II clinical trial from the NMPA in April 2020.

- *Adjusted study design.* For the Phase I dose-escalation trial, we expect to enroll approximately 33 patients to explore the safety and tolerability of dosimertinib and collect data for the PK analyses of dosimertinib. We plan to assign the enrolled patients to six groups, with one to three patients in the starting dose (20 mg/day) group and six patients in the 80 mg/day group, and three (default setting) or six patients in each of the remaining groups. The patients will be treated with dosimertinib, at a dosage of 20 mg/day, 40 mg/day, 80 mg/day, 160 mg/day, 200 mg/day and 240 mg/day, respectively. The trial would proceed from one dose level to the next if none of the three patients in a group experiences dose limiting toxicities (DLT) during the 28-day treatment cycle. If one of the original three patients in a group experiences DLT, three more patients would be added to the group and the trial would proceed to the next dose level only if none of the newly added three patients experience DLT. If one or more of the newly added three patients experience DLT, the dose-escalation trial would be terminated. If two or more patients in a dose level experience DLT, the dose-escalation trial would be terminated.

For the Phase II dose-expansion trial, we intend to enroll additional patients and collect additional information regarding the preliminary safety and efficacy of the selected dosage. We expect to enroll adult patients, with or without brain metastases, with locally advanced or metastatic NSCLC who are EGFR mutation-positive and have not received prior systemic therapy. The dose-expansion phase will consist of three cohorts: 80 mg, 160 mg, and 200 mg. The 80 mg cohort will enroll 20 to 30 patients, while the 160 mg and 200 mg cohorts will each enroll approximately 45 patients (20 to 30 patients with brain metastases in each cohort).

The primary endpoints for the trial are key safety and tolerance indicators for dosimertinib, such as number and severity of AEs and patient vital signs. Other endpoints include key pharmacokinetic and efficacy measures of dosimertinib. We have obtained ethical approvals for the clinical trial.

- *Trial status.* We initiated the trial in October 2022. In November 2023, we made a protocol adjustment about trial design for the Phase I dose-escalation trial by removing Osimertinib control group (considering mature PK data is available for osimertinib) and 120 mg/day dosimertinib group and adding 160 mg/day, 200 mg/day and 240 mg/day dosimertinib groups to better evaluate the safety, tolerance and pharmacokinetic characteristics of dosimertinib in higher doses. We received approval from the relevant ethics committee in January 2024. Prior to such protocol amendment, we had enrolled 10 patients (2 in the 20 mg/day group, 3 in 40 mg/day group and 5 in the 80 mg/day group) for the Phase I trial, whose data would be considered valid. We completed the Phase I dose escalation trial in May 2025. The completed clinical trial has met its primary and secondary endpoints, and there was no deviation from the clinical trial protocol.

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In April 2025, we communicated with the CDE regarding the amendment of design of Phase II clinical trial, by (i) amending the criteria of subjects to be enrolled to adult patients, with or without brain metastases, with locally advanced or metastatic NSCLC who are EGFR mutation-positive and have not received prior systemic therapy, and (ii) setting up three cohorts and increase the total number of subjects to be enrolled, instead of one cohort comprising 60 patients at a dosage of 80 mg/day. The CDE approved the trial design adjustment in May 2025, and we enrolled first patient for this Phase II trial in June 2025.

- *Phase I trial results:* No DLTs were observed in the dosimertinib 20 mg, 40 mg, 80 mg, 160 mg, 200 mg or the 240 mg dose group, overall safety profile was good, and we have also observed a good dose-related efficacy, as dosimertinib began to show efficacy from a dose of 20 mg, and the subjects in the 80 mg and above dose groups received more significant clinical benefits. In preclinical and early clinical studies, dosimertinib demonstrated efficacy comparable to osimertinib, with safety characteristics observed in preclinical and early-stage clinical studies. The tumor assessments of three patients in the 240 mg dose group showed significant efficacy, with one patient assessed as SD with shrinkage and the disappearance of non-target lesions in the brain, and two patients assessed as PR, with one of whom experiencing with the disappearance of three non-target lesions (left upper lobe of the lung, left lower lobe of the lung, and left pleura).

We expect to complete the Phase II trial in 2026.

Preclinical Studies

We conducted preclinical studies on pharmacodynamics, pharmacokinetics and toxicity of dosimertinib, and achieved favorable results to support the clinical development. The major preclinical studies were summarized as below:

- *Safety.* Nonclinical toxicity evaluation of dosimertinib included 28-day repeat-dose toxicity studies in male and female rats and beagle dogs with oral administration. In the toxicity study in rats, rats were orally administered dosimertinib at 4, 10, 20 and 40 mg/kg every day for 28 days. No observed adverse effect level (NOAEL) of this study was determined to be 4 mg/kg/day for male rats and 20 mg/kg/day for female rats. Highest non-severely toxic dose (HNSTD) of this study was determined to be 40 mg/kg/day for male rats and 20 mg/kg/day for female rats and no obvious toxicity reactions were observed at dose levels at or below the HNSTD. In the toxicity study in beagle dogs, beagle dogs were orally administered dosimertinib at 1, 3 and 6 mg/kg every day for 28 days. NOAEL of this study was determined to be 6 mg/kg/day. No obvious toxicity reactions were observed at dose levels at or below NOAEL.
- *Efficacy.* Dosimertinib showed dose-dependent inhibitory activities toward patient-derived xenocraft models of EGFR mutation-positive NSCLC cell lines BaF3, HCC827 and NCI-H1975 in preclinical studies. Among them, HCC827 was the most sensitive to dosimertinib. Efficacy in inhibition of growth of HCC827 in rat models was observed starting at a dosage of 0.5 mg/kg. With a dosage of 1 mg/kg, dosimertinib achieved a tumor growth inhibition (TGI) of 110.4% on HCC827. Efficacy in inhibition of growth of NCI-H1975 in rat models was observed starting at a dosage of 1.5 mg/kg. With a dosage of 3 mg/kg, dosimertinib achieved a TGI of 93.6% on NCI-H1975. Efficacy in inhibition of growth of BaF3 in rat models was observed starting at a dosage of 2.5 mg/kg. With a dosage of 5 mg/kg, dosimertinib achieved a TGI of 103.5% on NCI-H1975. At the same dosage level, dosimertinib exhibited dose-dependent inhibitory activities comparable to that of osimertinib on the three selected cancer cell lines.

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Material Communications and Next Steps

In May 2019, we had communications with the CDE regarding our Phase I/Phase II clinical trial of dosimertinib. In February 2020, we submitted the IND application to the NMPA. In April 2020, we obtained IND approval from the NMPA for the Phase I/Phase II clinical trial for dosimertinib. We communicated with the CDE regarding the amendment of the design of Phase II clinical trial in April 2025 and received approval in May 2025.

Other than the above, we have not had any material communications with the NMPA for dosimertinib for treatment of NSCLC. As of the Latest Practicable Date, no material adverse change had occurred with respect to the review or approval process of dosimertinib for the treatment of NSCLC.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET DOSIMERTINIB AS TREATMENTS FOR NSCLC SUCCESSFULLY.

ZSSW-136

ZSSW-136 is a novel inhibitor of topoisomerase I (TOPO1) enzymes which participate in the overwinding or underwinding of DNA and are particularly vulnerable to TOPO1 inhibitors during their cleavage reaction.

Over the past few decades, the most widely used TOPO1 inhibitor has been irinotecan, a camptothecin (CPT) derivative, which has become the backbone of various anti-tumor combination therapies. CPT and its derivatives, such as irinotecan, have been used as standard chemotherapeutic agents for more than 60 years. However, the improvement of CPT-based drugs has mainly focused on modifying the side chains of the CPT parent nucleus without changing the five-ring planar structure of the core. As such, the existing drugs mostly share the same type of core structure. CPT-based drugs face the problems of primary and post-treatment drug resistance, which is a shared challenge faced by the industry.

IND-enabling studies for ZSSW-136 are ongoing and new findings indicate that ZSSW-136 could significantly extend OS for cancer patients: ZSSW-136 demonstrated potent inhibition of both wild type and mutant TOPO1 enzymes, thus when used as first-line therapy it is expected to double the OS for patients compared to the current TOPO1 inhibitors (such as irinotecan). Consequently, our development plans for ZSSW-136 were expanded to build a stronger case for its potential use as first-line therapies for certain solid tumors (e.g. colon cancers and SCLC), and we are also exploring the potential of using ZSSW-136 as an ADC payload; with these additional studies ongoing, we now expect to submit an IND application in China in September 2026 and initiate clinical studies early 2027.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ZSSW-136 AS TREATMENT FOR SOLID TUMORS SUCCESSFULLY.

MTB-1806

MTB-1806 is a small-molecule drug candidate under development for AIS, whose typical cause is intracranial atherosclerotic disease (ICAD). AIS occurs when blood flow through a brain artery is blocked by a clot, *i.e.*, a mass of thickened blood. AIS is characterized by a sudden loss of blood circulation to an area in the brain, the corresponding lack of blood and oxygen supply resulting in nerve damage and loss of neurological function.

The incidence of AIS in China increased from 3.4 million in 2019 to 4.3 million in 2024 and is expected to further increase to 5.8 million in 2030. This suggests an increasing medical need for an effective and safe stroke drug.

We have commenced preclinical studies for MTB-1806. So far MTB-1806 has demonstrated its efficacy in pharmacodynamic studies, where it effectively reduced the infarction (the death of brain tissue) volume and the brain swelling volume and improved the neurobehavioral score. Additionally, under lower drug dosing regimens (10 mpk and 15 mpk), MTB-1806 was evaluated in a rat model of global ischemia-reperfusion injury, which is commonly associated with ischemic

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stroke. The study results indicated that MTB-1806 was associated with reductions in cerebral edema and neurological deficit scores in this preclinical model. The preclinical studies also demonstrated a good dose-effect relationship. The results of animal experiments suggest that the inhibition rate of MTB-1806 on the formation of cerebral infarction area after AIS is 75.3%, which is approximately three times of that of NBP. An *in vitro* stability test in human liver microsomes suggests that the half-life of MTB-1806 is 19.09 hours, which is approximately 19 times of that of NBP (below one hour), and, as such, suggests that MTB-1806 can be taken once daily. The results of acute toxicity test in mice suggest that the toxicity of MTB-1806 is lower than that of NBP, with MTB-1806's median lethal dose being about three times of that of NBP, suggesting a better safety profile. Furthermore, the use of MTB-1806 can reduce the area of cerebral ischemic infarction; the area of cerebral ischemia and reperfusion of mice with cerebral ischemia and reperfusion is reduced to 12.0% by MTB-1806, which is smaller than that of NBP which is 37.5%. MTB-1806 also demonstrated superior PK to NBP in terms of *in vivo* exposure and oral bioavailability in rat models. No significant abnormality in body weight was observed in dog models after a single intragastric administration of MTB-1806, with a MTD (the highest dose of a drug or treatment that does not cause unacceptable side effects) of over 80 mg/kg/day. There was an obvious toxicokinetics-dose relationship without significant gender difference. All animal models showed good tolerance to MTB-1806 and no abnormalities were observed before and after drug administration.

We expect to complete our preclinical studies and submit IND application in the second half of 2026.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET MTB-1806 SUCCESSFULLY.

ZS-2004

We are developing ZS-2004, a GRPR—targeting antagonist as a theranostic radioligand for molecular imaging and targeted radionuclide therapy in GRPR-expressing malignancies, including lung, breast, and prostate cancers. By leveraging GRPR overexpression in certain tumor types, ZS-2004 is designed to enable tumor visualization for diagnostic imaging and to deliver β -particle radiation from lutetium-177 to tumor cells, inducing DNA damage that may lead to tumor cell death.

Preclinical studies have evaluated the pharmacokinetics, biodistribution, efficacy, and safety of ZS-2004. *In vivo* PET/SPECT imaging in a PC-3 mouse tumor model demonstrated clear tumor accumulation with favorable tumor-to-nontarget (T/NT) ratios, supporting robust tumor visualization. Biodistribution studies further confirmed preferential uptake in tumors with limited retention in normal tissues and organs. In pharmacology studies, ZS-2004 produced potent tumor growth inhibition in a PC-3 cell-derived xenograft (CDX) mouse model (TGI = 96.9% on Day 52, Q2W $\times$ 3). In nonclinical safety assessments, ZS-2004 was well tolerated. In mouse models, no significant systemic toxicity was observed at doses up to 98-fold higher than the human equivalent dose (HED) of the anticipated maximum clinical therapeutic dose.

We expect to submit IND application for Phase I clinical trial in 2027.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ZS-2004 SUCCESSFULLY.

ZS-1004

ZS-1004 is a PSMA—targeting dual-payload antibody—drug conjugate (ADC) composed of a proprietary humanized monoclonal antibody, a highly hydrophilic linker, and an optimized dual-payload configuration with controlled overall drug loading and a tuned payload ratio designed to improve tolerability. Upon binding to PSMA on tumor cells, ZS-1004 is rapidly internalized and undergoes lysosomal processing to release two cytotoxic payloads—a microtubule inhibitor and a topoisomerase I inhibitor—thereby enabling coordinated inhibition of tumor cell proliferation and induction of tumor cell death.

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ZS-1004 exhibits a highly homogeneous conjugate profile, strong plasma stability, and favorable PK properties in preclinical studies. Following binding to PSMA, ZS-1004 undergoes efficient internalization and payload release, resulting in potent tumor cell killing. In the 22Rv1 cell-derived xenograft (CDX) mouse model, a single intravenous administration of ZS-1004 at 2 mg/kg produced potent and durable tumor growth inhibition through Day 27 post-dose.

We expect to submit IND application for Phase I clinical trial in 2027.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ZS-1004 SUCCESSFULLY.

OUR TECHNOLOGY TRANSFER ARRANGEMENTS AND COLLABORATIONS

Zhengzhou University Technology Transfer Agreement

Azvudine, our Core Product, was initially developed by Zhengzhou University, a public university in China. Beijing Xingyu Zhongke Investment Co., Ltd. (北京興宇中科投資有限公司) (“Xingyu Zhongke”), a company controlled by Mr. Wang, entered into a technology transfer agreement with Zhengzhou University on December 16, 2011 (the “Azvudine IP Transfer Agreement”) to acquire intellectual property rights in azvudine.

The table below summarizes key terms in the Azvudine IP Transfer Agreement:

- *Scope of Technology Transfer.* Zhengzhou University transfers all rights in the core patent of azvudine (patent number ZL200710137548.0) and any existing and future NMPA approvals of azvudine to Xingyu Zhongke. Xingyu Zhongke is the sole right holder of such rights and is entitled to develop, apply for clinical trial/registrational approval for, manufacture and seek collaborations for azvudine for its treatment of HIV, HBV as well as HCV infections globally. Parties will invest together to develop azvudine for the treatment of cancers. Zhengzhou University also agrees to transfer any subsequent patent rights related to azvudine in jurisdictions other than China to Xingyu Zhongke with no additional conditions; alternatively, both parties will apply for such patent rights as co-applicants.
- *Clinical Trial and Regulatory Registration.* Xingyu Zhongke will be responsible for subsequent clinical trials and registration work, with full technical support from Zhengzhou University. Xingyu Zhongke bears all costs associated with such registrational work. Both parties shall be named as applicants for any subsequent NMPA registration applications.
- *Transfer Fee and Payment Schedule.* The transfer fee for the intellectual property rights of azvudine is RMB40.0 million, which shall be paid in three installments: (i) the first installment of RMB5.0 million shall be paid within 30 days after the execution of the Azvudine IP Transfer Agreement. We have completed such payment in January 2012; (ii) the second installment of RMB7.0 million shall be paid within 30 days after the ownership of the core patent of azvudine have been properly transferred. We have completed such payment in February 2014; (iii) the final installment of RMB28.0 million shall be paid within 30 days after azvudine obtained the IND approval for HIV. We have completed such payment in November 2018 and April 2021, respectively, as later agreed among the relevant parties. All three installments have been paid using our working capital.
- *R&D Costs.* Xingyu Zhongke bears all R&D costs associated with the development of azvudine as a Class 1.1 new drug, including those incurred by Zhengzhou University for IND applications and approved by Xingyu Zhongke in writing.
- *Obligations of Zhengzhou University.* Zhengzhou University shall complete all R&D work for azvudine until it obtains the IND approval.

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- *Confidentiality.* Both parties are under strict confidentiality with respect to all research and registrational information and documentations, except for the publicly available information that was made public by Zhengzhou University prior to the Azvudine IP Transfer Agreement.
- *Term.* The agreement became effective since December 16, 2011 and shall terminate upon the expiration of the core patent of azvudine.

After Henan Genuine, our PRC operating company, was established in 2012, Xingyu Zhongke and Zhengzhou University further entered into a supplemental agreement on May 14, 2013 (the “Azvudine Novation Agreement”) to novate the intellectual property rights under the Azvudine IP Transfer Agreement and transfer the relevant intellectual property rights to Henan Genuine. The Azvudine Novation Agreement provides that Xingyu Zhongke transfers all rights and obligations under the Azvudine IP Transfer Agreement to Henan Genuine.

On September 1, 2023, Henan Genuine obtained a written confirmation from Zhengzhou University (the “**Written Confirmation**”) to clarify the parties’ original intentions for the Azvudine IP Transfer Agreement. Pursuant to the Written Confirmation, Zhengzhou University has confirmed that (i) the transfer of the intellectual property rights of azvudine pursuant to the Azvudine IP Transfer Agreement was complete and unqualified, and entails full proprietary and derivative rights in azvudine for any possible indications; (ii) the Azvudine IP Transfer Agreement did not limit the scope of the transfer to the treatment of HIV, HBV and HCV infections, which were mentioned in the Azvudine IP Transfer Agreement for the purpose of memorializing the indications under development for azvudine at the time of the agreement; and (iii) since the date of the Azvudine IP Transfer Agreement, with respect to other indications such as cancer, the only achievement from Zhengzhou University’s R&D of azvudine was a PRC indication patent (patent number ZL201010506595.X, the “**Azvudine Cancer Patent**”), which Zhengzhou University transferred to Henan Genuine in July 2023, and it has relinquished the right to co-invest in the R&D of azvudine for those other indications.

As a novel nucleoside compound with a dual-target mechanism, azvudine’s structural characteristics suggest potential activity in inhibiting tumor cell proliferation. Zhengzhou University identified that azvudine inhibits viral replication by terminating viral DNA chain elongation and therefore explored its anti-tumor potential in parallel with its anti-HIV research, which identified certain anti-tumor activity. Such approach is consistent with common practice in innovative drug development to explore a compound’s broader clinical potential, as advised by Frost & Sullivan. The Azvudine Cancer Patent provides an initial basis for our understanding of the potential anti-tumor effects of azvudine in both blood cancers and solid tumors. We acquired such cancer-related indication patent with a view to developing azvudine for such indication free from any future restrictions that may arise in the course of expanding into more indications of azvudine. Our continuing R&D of azvudine on the cancer indications will be based solely on our self-developed know-how, and will not depend on the transferred indication patent. In addition, such patents form part of our broader intellectual property portfolio relating to azvudine’s oncology indications and support our ability to further develop and protect derivative technologies, such as combination therapies.

Based on the Azvudine IP Transfer Agreement, the Azvudine Novation Agreement and the Written Confirmation, our PRC IP Advisors, are of the view that the transfer of the intellectual property rights of azvudine to Henan Genuine was complete as of the date of the Azvudine Novation Agreement. Therefore, according to the PRC IP Advisors, (i) Henan Genuine has the full right to conduct any subsequent research, development and commercialization of azvudine, its preparation methods and its pharmaceutical use for any potential indications; (ii) Henan Genuine is also entitled to independently improve or further develop the transferred patent rights and become the sole right holder of any substantive or innovative technological advances arising from such development and intellectual property rights contained therein; and (iii) upon the transfer, Zhengzhou University is no longer entitled to commercially exploit the transferred patent rights in any manner unless permitted by Henan Genuine. Therefore, as advised by our PRC IP Advisors, we have the independence, autonomy and full rights in the R&D, commercialization and the ownership of intellectual properties of azvudine arising from our subsequent R&D in Chinese Mainland and other overseas markets. Additionally, as advised by our PRC IP Advisors based on the Core Product FTO Analysis, there are currently no patents or pending patent applications that would impede our R&D or commercialization activities relating to azvudine. Our PRC IP Advisors have also advised that

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based on the indications for azvudine currently under development, there is no requirement for us to acquire any other patents from third parties to conduct further R&D and commercialization activities for azvudine. Accordingly, our Directors are of the view that, we have sufficient intellectual property protection for azvudine, and do not consider necessary to acquire any further intellectual properties from third parties to advance the R&D and commercialization of azvudine.

Subsequent to the acquisition of patents under the Azvudine IP Transfer Agreement, Azvudine Novation Agreement and Written Confirmation, we have been conducting R&D of azvudine independently from Zhengzhou University or any other third parties, except for certain CROs engaged to conduct ancillary and supporting R&D activities in line with industry norm.

Meitaibao Technology Transfer Agreement

We acquired 11 patents relating to CL-197, dosimertinib and MTB-1806 from Henan Meitaibao Biological Pharmaceutical Co., Ltd.* (河南美泰寶生物製藥有限公司) (“Meitaibao”), which is a biotech company primarily focused on drug R&D founded and controlled by Dr. Du in July 2015, who served as its chief executive officer until December 2018. Dr. Du was extensively involved in the development and a primary inventor of the relevant patents. It was considered mutually beneficial for Meitaibao and our Group if Dr. Du could bring the 11 patents to our Group and continue leading the R&D activities for CL-197, dosimertinib and MTB-1896.

In light of the above considerations, on January 18, 2019, the same date when Dr. Du joined our Group, Henan Genuine entered into a technology transfer agreement with Meitaibao (as supplemented on February 20, 2019, July 25, 2019, June 1, 2020 and December 8, 2021 and also clarified by a clarification agreement dated June 20, 2020; collectively, the “Meitaibao Technology Transfer Agreement”) to acquire from Meitaibao the 11 patents to develop and commercialize the corresponding drug candidates. We believe this acquisition further supplements our product portfolio and strengthens our R&D capacities.

The table below summarizes key terms in the Meitaibao Technology Transfer Agreement:

- *Scope of Technology Transfer.* Meitaibao transfers all rights in 11 patents (the “Meitaibao Patents”) to Henan Genuine. From the effective date of the patent transfer registration, all rights to the Meitaibao Patents shall be transferred to Henan Genuine.
- *Transfer Fee and Payment Schedule.* The transfer fee for rights in the Meitaibao Patents is RMB124.0 million, which shall be payable in multiple installments: (i) a deposit of RMB50.0 million, which shall be payable in multiple installments. We have completed such payment installments upon signing of the Meitaibao Technology Transfer Agreement, and in December 2019, November 2020 and February 2021, respectively; and (ii) the remaining amount of RMB74.0 million shall be paid subject to the condition that preclinical studies have been completed and IND approval for a Phase I clinical trial has been obtained for any two drug candidates developed from the Meitaibao Patents, and the payment will be made within 14 days upon obtaining such IND approval for the second drug candidate as mentioned above. We have completed such payment in October 2022. All installments have been paid using our working capital.
- *R&D Costs.* Henan Genuine bears all existing and future R&D costs associated with the R&D work for each of the indications of the relevant drug candidates.
- *Non-Competition.* Meitaibao and its affiliates agree that they will not, directly or indirectly, engage in the same or similar business activities as operated by Henan Genuine; nor will they engage any third parties to conduct, directly or indirectly, such same or similar business activities as operated by Henan Genuine; unless with prior approval by Henan Genuine in writing.
- *Confidentiality.* Both parties are under strict confidentiality with respect to any non-public information, trade secrets and other information disclosed in the Meitaibao Technology Transfer Agreement.
- *Term.* The agreement became effective from January 18, 2019 and shall terminate upon mutual agreement by the parties. The agreement may be terminated unilaterally by Henan Genuine if a breach of the agreement by Meitaibao would constitute a triggering event leading to early termination as stipulated in the agreement.

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As advised by our PRC IP Advisors, we have obtained all the patent rights of Meitaibao Patents for our independent R&D and commercialization of the relevant drug candidates including CL-197, dosimertinib and MTB-1806.

Beijing Union Collaboration Agreements in Russia and Ukraine

Henan Genuine entered into a framework agreement with Beijing Union, a pharmaceutical company primarily engaged in the activities of drug R&D, manufacturing and commercialization, on April 18, 2020 (as supplemented on May 10, 2022, and together with a confidentiality agreement entered into by the parties on April 13, 2020, the “April 2020 Collaboration Agreements”) to authorize Beijing Union to fully carry out registration applications, clinical trials and application matters of azvudine in Russia and Ukraine. Beijing Union will be the MAH and act as the manufacturer of azvudine in Russia and Ukraine after it obtains marketing approval in these countries. This collaboration was entered into at the early stage of the COVID-19 pandemic in 2020, when the number of patients in China was limited and the Company sought to conduct overseas clinical trials to obtain sufficient data for NDA application and commercialization. At that time, we had limited experience in overseas registration, clinical trials and commercialization. Beijing Union, which had experience in international drug registration and clinical practice with products marketed in Russia and Ukraine, and had established a trusted relationship with us as the NMPA-approved contract manufacturer of azvudine tablets, enabled rapid project initiation and reduced the time required to identify and engage unfamiliar overseas partners, thereby improving decision-making efficiency, lowering communication costs and mitigating execution risks. As of the Latest Practicable Date, Beijing Union had completed the Phase III clinical trial of azvudine for treating COVID-19 in Russia and obtained marketing approval from the Ministry of Health of the Russian Federation in February 2023. See “—Our Product Portfolio—Azvudine—Our Core Product—COVID-19—Summary of Clinical Trials” for details. As of the Latest Practicable Date, we had not initiated any clinical trials in Ukraine and do not intend to do so in the foreseeable future.

The table below summarizes key terms in the April 2020 Collaboration Agreement:

- *Territory.* Russia and Ukraine.
- *Clinical trial and registration application collaboration.* Henan Genuine authorizes Beijing Union to fully carry out registration applications, clinical trials and other application matters of azvudine for all possible indications (including the COVID-19 indication) in Russia and Ukraine.
- *Registration application support.* Beijing Union shall provide the clinical trial data for the clinical trial conducted in Russia to Henan Genuine for its registration application submitted in China. In addition, Beijing Union shall provide the authentic and complete clinical trial data to Henan Genuine in accordance with the requirements set forth by the relevant regulatory authorities in reviewing the registration applications to be submitted in jurisdictions other than Russia and China.
- *Technical consulting service fee.* Henan Genuine shall pay Beijing Union a technical consulting service fee in multiple installments: (i) RMB5.2 million payable upon signing of the April 2020 Collaboration Agreement; and (ii) based on 50% of the clinical trial and registration costs incurred by Beijing Union in Russia and to be confirmed by the parties, within 15 days after Henan Genuine obtained the NMPA approval for azvudine for the COVID-19 treatment with the support of the clinical trial data provided by Beijing Union. We have made the payment of RMB4.4 million in November 2023.
- *Rights of Beijing Union in Russia and Ukraine.* Beijing Union will be the MAH and act as the manufacturer of azvudine in Russia and Ukraine after it obtains marketing approval in these countries.
- *Profit allocation upon marketing approval.* After azvudine is approved for marketing in a jurisdiction by the local competent authority, the net profit generated from the sales of azvudine in Russia and Ukraine shall first be used to reimburse Beijing Union for the actual expenses incurred in registration, certification and clinical trial matters in Russia (excluding the technical consulting service fee to be paid by Henan Genuine to Beijing Union) and then shared among the parties as agreed upon.

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Tripartite Collaboration Agreements in Brazil and Other Regions of South America

Henan Genuine entered into a tripartite framework agreement with Beijing Union and an Independent Third Party (“**Brazil Agent**”) agent on June 5, 2020 (the “June 2020 Framework Agreement”) to authorize Beijing Union to cooperate with the Brazil Agent to carry out registration applications, clinical trials and application matters of azvudine for treating COVID-19 in Brazil and the Union of South American Nations (UNASUR).

In light of the parties’ collaboration following the June 2020 Framework Agreement, on November 8, 2021, Henan Genuine entered into a supplemental collaboration agreement (as further supplemented on January 28, 2022 and May 8, 2022; collectively, the “November 2021 Agreement”) with Beijing Union and an affiliate of the Brazil Agent (“**Brazil Agent Affiliate**”), who is also an Independent Third Party, as a supplement to the June 2020 Framework Agreement (together, the “Collaboration Agreements”). As of the Latest Practicable Date, the Phase III clinical trial of azvudine for treating COVID-19 in Brazil was completed. See “—Our Product Portfolio—Azvudine—Our Core Product—COVID-19—Summary of Clinical Trials” for details.

The table below summarizes key terms in the Collaboration Agreements:

- *Territory.* Brazil and the other regions of South America (as defined therein).
- *Clinical trial and registration application collaboration.* Henan Genuine authorizes Beijing Union to cooperate with the affiliate to carry out registrations, clinical trials and application matters of azvudine for COVID-19 in Brazil and the other regions of South America.
- *Clinical trial data ownership.* Henan Genuine is entitled to 50% of the ownership in the clinical data from the Phase III clinical trial of azvudine for treating COVID-19 in Brazil (“the Brazil Clinical Data”).
- *Rights of Beijing Union.* After azvudine for the COVID-19 indication is approved for marketing in Brazil, Beijing Union shall act as the manufacturer for such product to be sold in Brazil.
- *Rights of the Brazil Agent Affiliate.* After azvudine for the COVID-19 indication is approved for marketing in Brazil, the Brazil Agent Affiliate shall be the MAH of azvudine in Brazil and have exclusive marketing rights in Brazil and the other regions of South America.
- *Profit allocation upon marketing approval.* The net profit generated from the export of azvudine from China to Brazil and the other regions of South America shall first be used to reimburse Beijing Union and the Brazil Agent Affiliate for the actual expenses incurred in registration and clinical trial matters in Brazil and then shared among us, Beijing Union and Brazil Agent Affiliate as agreed upon. The affiliate shall bear the costs related to and be entitled to the profit generated from the sales of azvudine after export.

Pursuant to the supplemental agreement dated May 8, 2022, we agreed to pay Brazil Agent Affiliate RMB30 million to compensate its costs incurred for the clinical trials in Brazil, which was settled in May 2022.

Beijing Union completed the Phase III clinical trial of azvudine for treating COVID-19 in Russia and Brazil, respectively, and was involved in the communications with the competent authority in Russia. While we do not consider Russia, Ukraine, Brazil and the other regions of South America to be main target markets for our business and agreed to conduct the clinical trial for the treatment of COVID-19 therein mainly due to practical concerns, *i.e.*, the lack of a large COVID-19 positive population in Chinese Mainland at the time, we believe our collaboration with Beijing Union, the agent and the affiliate in these territories is win-win for all parties. Particularly, such collaboration has demonstrated strong contribution to the value maximization of azvudine in that

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the NMPA did refer to the data of the clinical trial conducted in Russia in granting the conditional approval to azvudine for the COVID-19 indication expansion and requested that the Company submit the final trial report upon completion of this clinical trial.

Fosun Pharma Strategic Cooperation Agreements

Entrance into the Collaboration and Commercial Rationale

On July 25, 2022, Henan Genuine entered into a strategic cooperation agreement (as supplemented on August 26, 2022, the “**Fosun Pharma Agreements**”) with Fosun Pharmaceutical Industrial, a subsidiary of Fosun Pharma, with respect to, among other things, Fosun Pharmaceutical Industrial’s exclusive commercialization of azvudine, the key terms of which are summarized as follows:

- *Cooperation Regions.* (i) Region I: Chinese Mainland, excluding Hong Kong, Macau and Taiwan; and (ii) Region II (together with Region I, the “Cooperation Regions”): rest of the world and excluding Russia, Ukraine, Brazil and other South American countries and regions. During the term of Fosun Pharma Agreements and up to the Latest Practicable Date, no supplemental agreement regarding the collaboration in Region II has ever been entered into between Fosun Pharmaceutical Industrial and us.
- *Cooperation Scope of Indications.* (i) the treatment and prevention of COVID-19; and (ii) the treatment and prevention of HIV infection.
- *Cooperation Product.* Within the Cooperation Scope of Indications, the Cooperation Product includes the API and tablets of azvudine and all products in other formulations containing the API of azvudine, excluding a composite product candidate, developed by Henan Genuine, composed of azvudine and a molecule newly developed by Henan Genuine for the treatment of HIV infection (the “Excluded Product”).
- *Cooperation.* Henan Genuine will cooperate with Fosun Pharmaceutical Industrial exclusively as follows (the “Cooperation”): (i) in Region I, Fosun Pharmaceutical Industrial shall be primarily responsible for the post-marketing clinical development of the Cooperation Product and Henan Genuine shall be primarily responsible for the preclinical study, production and supply of the Cooperation Product. Fosun Pharmaceutical Industrial shall have the exclusive commercialization right in respect of the Cooperation Product for Region I; and (ii) the parties may enter into supplemental agreements for cooperation in Region II, where Fosun Pharmaceutical Industrial will lead preclinical pharmacological and toxicity studies, clinical development and registration matters for the Cooperation Product, and the parties shall further discuss and arrange other preclinical studies, manufacturing and supply. Fosun Pharmaceutical Industrial shall have the exclusive commercialization right in respect of the Cooperation Product for Region II if such supplemental agreement is entered into. No supplemental agreement regarding cooperation in Region II was reached during the term of Fosun Pharma Agreements.
- *Development of Cooperation Product.*

Region I:

– Treatment of COVID-19: The parties agree to establish a joint management committee to negotiate and coordinate on matters related to clinical trial, registration, drug safety monitoring, production and supply as well as commercialization of Cooperation Product for the treatment of COVID-19 in Region I. Fosun Pharmaceutical Industrial shall be responsible for conducting the clinical studies the NMPA may require after the conditional approval for the treatment of COVID-19.* Henan Genuine shall be responsible for preclinical study (if necessary) and research on process, production and quality matters related to the Cooperation Product.

* As of the Latest Practicable Date, the NMPA had not imposed any additional post-approval clinical study requirement on the Company.

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– Prevention of COVID-19: The parties agree to jointly conduct the prospective clinical studies on azvudine for the prevention of COVID-19 in Region I under the guidance of the joint management committee.

– Treatment of HIV infection: Henan Genuine shall be responsible for conducting the Phase III clinical trial of azvudine as required by the NMPA after the conditional approval for the treatment of HIV infection.

Region II:

If parties enter into a supplemental agreement for cooperation in Region II, Fosun Pharmaceutical Industrial shall be responsible for the relevant clinical trial and registration matters for the Cooperation Product for the treatment of COVID-19 therein.

- *Cooperation Fee and Payment Arrangement.*

No later than five business days after the execution of the Fosun Pharma Agreement, Fosun Pharmaceutical Industrial shall pay RMB100 million to Henan Genuine, which is a precondition for the parties to carry out due diligence and subsequent cooperation as set forth in the Fosun Pharma Agreement.

In relation to the cooperation within Region I, Fosun Pharmaceutical Industrial shall pay Henan Genuine RMB399.5 million within seven business days after completion and satisfaction of prerequisite due diligence and evaluation by Fosun Pharmaceutical Industrial as set forth in the Fosun Pharma Agreement.

Fosun Pharmaceutical Industrial will further evaluate the suitability of cooperation in Region II through agreed-upon due diligence and evaluation and decide whether to enter into a supplemental agreement for such cooperation. Fosun Pharmaceutical Industrial shall, within ten business days after such supplemental agreement (if applicable) becomes effective, pay Henan Genuine RMB300 million for Region II.

- *Development Costs.*

Region I:

– Treatment of COVID-19: The parties agree that for the COVID-19 treatment, the R&D costs of the Cooperation Product with respect to preclinical studies, manufacturing and quality research in Region I shall be borne by Henan Genuine, while Fosun Pharmaceutical Industrial shall be responsible for the costs related to any post-approval clinical studies the NMPA may require after the conditional approval for the treatment of COVID-19.

– Prevention of COVID-19: The parties agree that for the prospective clinical studies to be conducted for the prevention of COVID-19, Fosun Pharmaceutical Industrial and Henan Genuine shall share the relevant clinical research costs on a 60%:40% basis, provided that such clinical studies have been confirmed by the joint management committee and the proposal of which has been approved by the relevant regulatory authorities.

– Treatment of HIV infection: Henan Genuine shall be responsible for the costs related to the Phase III clinical trial of azvudine as required by the NMPA after the conditional approval for the treatment of HIV infection.

Region II:

If the parties enter into a supplemental agreement for cooperation in Region II for the treatment of COVID-19, Fosun Pharmaceutical Industrial shall be responsible for the costs related to the preclinical pharmacology and toxicology studies, as well as the clinical trials and registration matters, with the costs of the other preclinical studies to be determined by the parties.

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- *Commercialization Costs.* The commercialization costs of the Cooperation Product in the Cooperation Regions for the Cooperation Scope of Indications will be borne by Fosun Pharmaceutical Industrial.
- *Profit Sharing.* The parties agree that the gross profits generated from sales of the Cooperation Product in Region I shall be shared by Fosun Pharmaceutical Industrial and Henan Genuine on a 50%:50% (if the sales were made through centralized procurement channels) or 55%:45% (if the sales were made through channels other than the centralized procurement channels) basis.

The parties further agree that the gross profits generated from sales of the Cooperation Product in Region II shall also be shared by Fosun Pharmaceutical Industrial and Henan Genuine, with the detailed sharing method and proportion to be further agreed by the parties in supplemental agreements.

- *Intellectual and Proprietary Rights.* Henan Genuine grants an exclusive license to Fosun Pharmaceutical Industrial to use its IP rights with respect to the Cooperation Product for the latter to conduct development and commercialization activities for the Cooperation Scope of Indications in Cooperation Regions. The parties agree that within Cooperation Regions, any regulatory approvals for conducting clinical trials and manufacturing of the Cooperation Product for the COVID-19 indications and any patent arising therein shall belong to Henan Genuine.

Henan Genuine shall own full rights in any inventions, patents and any other associated IP rights (whether or not such right is patentable) that are envisioned, discovered, developed or otherwise created jointly by the parties and/or their affiliates under the Fosun Pharma Agreements. Fosun Pharmaceutical Industrial is authorized to use such rights at no cost pursuant to the Fosun Pharma Agreements.

- *Manufacturing and Supply of Cooperation Product.* In relation to the cooperation within Region I, Henan Genuine shall be responsible for the manufacturing of the Cooperation Product with a sufficient production capacity to meet the needs of Fosun Pharmaceutical Industrial in Region I. In relation to the cooperation within Region II, Henan Genuine shall firstly engage Fosun Pharmaceutical Industrial to manufacture by its manufacturing facilities and provide Fosun Pharmaceutical Industrial raw ingredients for its production needs. Henan Genuine shall make commercially reasonable efforts in reducing the manufacturing costs of the Cooperation Product. Henan Genuine shall be responsible for any additional costs if the actual supply price exceeds the supply price range as stipulated in the Fosun Pharma Agreement.
- *Priority Cooperation Right.* In respect of the Excluded Product and other indications of the Cooperation Product outside the Cooperation Scope of Indications, if Henan Genuine seeks external collaboration on such matters, Fosun Pharmaceutical Industrial shall have the priority cooperation right under the same conditions.
- *Term.* The Fosun Pharma Agreements shall be effective from the date of execution by the parties and does not have a fixed term. It may be terminated by mutual agreement of the parties or other termination events as stipulated in the Fosun Pharma Agreements.

After azvudine was approved for the treatment of HIV infection and COVID-19 in China, we selected Fosun Pharmaceutical Industrial to be our commercialization partner in China and potentially Region II mainly considering its comprehensive industrial chain integration capabilities and global business experience that could help us quickly expand the market and promote product sales, which is in line with the industry practice, according to Frost & Sullivan. Fosun Pharmaceutical Industrial was not involved in any clinical trial of azvudine or any material communications with competent authorities.

Furthermore, we believe it is prudent to collaborate with a large pharmaceutical company like Fosun Pharmaceutical Industrial to ensure a successful commercial launch of azvudine for the treatment of both COVID-19 and HIV infection in China at the moment because (i) its established sales network and extensive commercialization experience would enable us to quickly commence

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large-scale sales of azvudine and respond to the urgent demand for azvudine for the treatment of COVID-19 in a timely manner; (ii) COVID-19 and HIV are both viral infections posing significant socioeconomic burden on the public, which makes it industry practice to collaborate with large pharmaceutical companies capable of organizing large-scale sales nationally to ensure smooth distribution; and (iii) it is cost-effective and administratively efficient to work with the same partner for the sales of azvudine for both indications since HIV and COVID-19 drugs overlap significantly in their distribution channels. We believe our collaboration with Fosun Pharmaceutical Industrial is win-win for both parties and improves the probability of successful commercialization of azvudine.

Return and Exchange Arrangement in 2023

In November 2023, in light of the COVID-19 drug market condition, we and Fosun Pharmaceutical Industrial began discussions to reach a return and exchange arrangement of near-expiry azvudine tablets. We and Fosun Pharmaceutical Industrial each issued an azvudine sales confirmation memorandum to the other party to reflect such return and exchange arrangement between the parties thereafter, see “Financial Information—Discussion of Certain Components of Consolidated Statements of Profit or Loss and Other Comprehensive Income—Revenue” for details.

Termination of Collaboration and Commercial Rationale

On September 26, 2024, we entered into the Amendment Agreement with Fosun Pharmaceutical Industrial after amicable negotiations. The Amendment Agreement outlines an updated arrangement for the collaboration in Region I (the “**Updated Commercialization Arrangement**”), under which, among other things, (i) we have regained the exclusive commercialization rights and other rights granted to Fosun Pharmaceutical Industrial in Region I (i.e. Chinese Mainland). As a result, we have become the sole owner of the commercialization right of azvudine in Region I, while we are no longer obligated to manufacture azvudine and ensure sufficient product supply; (ii) Fosun Pharmaceutical Industrial no longer possesses the right to use any clinical trial information, technologies or IP rights relating to azvudine, and neither party has any obligation to share data in this regard; (iii) Fosun Pharmaceutical Industrial is no longer obligated to carry out the research and development of clinical studies on the azvudine; (iv) Fosun Pharmaceutical Industrial no longer has the pre-emptive right to collaborate with us regarding the joint development and commercialization of the azvudine in Region I for other indications or combination therapy for the treatment of HIV infections; and (v) all other rights and obligations of the parties under the Fosun Pharma Agreements have been terminated unless otherwise agreed. This strategic shift reflects the evolving market conditions and our commitment to fully control the commercialization process for azvudine, aligning with our broader focus on antiviral drug development. In addition, under the Updated Commercialization Arrangement, we have agreed to pay Fosun Pharmaceutical Industrial (i) an upfront fixed payment of RMB60 million, and (ii) a subsequent sales-based payment, calculated as 10% of our net sales of azvudine for the treatment and prevention of COVID-19 and HIV infections generated in Region I within a period of five years subsequent to the effective date of the Amendment Agreement, as the consideration for Fosun Pharmaceutical Industrial’s investments and expenditures incurred for the historical collaboration. The determination and calculation of such payments has reflected our considerations and analysis of the market conditions and risks as a result of mutually agreed-upon, commercially sound judgment between the two parties. In terms of azvudine already sold to distributors as of the date of the Amendment Agreement, Fosun Pharmaceutical Industrial and us have agreed to share the profits at ratios as stipulated in the Amendment Agreement.

Since September 26, 2024 when the Amendment Agreement took effect, we and Fosun Pharmaceutical Industrial had been proactively liaising with the existing distributors of azvudine engaged by Fosun Pharmaceutical Industrial to make handover arrangements that reflect the Updated Commercialization Arrangement (the “**Handover Arrangements**”), including, among other things, terminating the distribution agreements between the distributors and Fosun Pharmaceutical Industrial and entering new distribution agreements between the distributors and us. As of the Latest Practicable Date, we had completed the Handover Arrangements.

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To the best of our knowledge, both parties believe that it would be mutually beneficial for us to retain the commercialization right of azvudine in Chinese Mainland under the Updated Commercialization Arrangement considering the following factors:

- (i) in August and October 2022 when the Fosun Pharma Agreements were entered into, (a) it was under severe COVID-19 pandemic, (b) Fosun Pharmaceutical Industrial was developing antiviral vaccines, and decided to in-license azvudine, an antiviral therapeutic product, to enhance its product pipeline in antiviral area, and (c) it was commercially sensible at that time for us to collaborate with such a large pharmaceutical company, to quickly capture the market opportunities and ensure a successful commercial launch of azvudine for the treatment of COVID-19 by leveraging its established sales network and extensive commercialization experience;
- (ii) since the implementation of normalized epidemic prevention and control measures in Chinese Mainland at the end of 2022, Fosun Pharmaceutical Industrial had adjusted its strategies regarding the development of antiviral products. In light of that, continuing its commercialization plan for a single product, azvudine, would be less cost-efficient, as there are no other products to share the costs and expenditures to develop and maintain distribution channels and end customers;
- (iii) conversely, antiviral drugs have always been a primary focus in our business strategies. Despite the collaboration arrangement with Fosun Pharmaceutical Industrial, we have made substantial investments in the R&D of new antiviral drug candidates;
- (iv) we have also been actively exploring the indication expansions of azvudine into cancer and combination therapies; and
- (v) we have been building up our own commercialization capabilities including formation of an in-house commercialization team to duly execute our proposed commercialization plan for drug candidates, including azvudine.

As the license-out of commercialization right of azvudine has always been the core subject matter of this collaboration between both parties, all the other ancillary arrangements under the Fosun Pharma Agreements were also terminated by the Amendment Agreement. The termination of such collaboration was out of a decision based on the change of market environment and the intended business focuses of both parties. In light of the abovementioned factors, we do not consider such termination will have a material adverse impact on our business operations and financial position.

Furthermore, with our independent R&D capability and exclusive R&D rights over azvudine during the Track Record Period regardless of our collaboration with Fosun Pharmaceutical Industrial and except for certain R&D responsibilities (namely registration, clinical trials, and clinical application) we granted to Beijing Union and third party agents in certain regions as mentioned above, we have effectively and independently realized the advancements of clinical stages of azvudine for different indications, especially expanded indications including blood cancers and solid tumors, which are evidenced by positive feedbacks from the NMPA. In particular, we have completed the Phase I clinical trial of azvudine for the treatment of solid tumors, based on which (i) we submitted the IND application for the Phase II clinical trial of azvudine monotherapy for the treatment of blood cancers, received acceptance notification in September 2025 and obtained the IND approval in December 2025, (ii) we submitted the IND application of azvudine + dosimertinib for the treatment of NSCLC in July 2025, and received the IND approval in September 2025, and (iii) we submitted an IND application of azvudine + anti-PD-1 for the treatment of liver cancer and colorectal cancer in December 2025, and obtained the IND approval in February 2026. See “—Our Product Portfolio” in this section for details.

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After the termination of collaboration with Fosun Pharmaceutical Industrial by entering into the Amendment Agreement, and pursuant to the Beijing Union collaboration agreements in Russia and Ukraine and tripartite collaboration agreements in Brazil and other regions of South America, we set out the rights of us and other parties in azvudine as follows:

Indication	Regions	R&D Allocation	MAH	Commercialization Rights
HIV Infection	Global (excluding Russia and Ukraine)*	Our Company	Our Company	Our Company
	Russia and Ukraine	Beijing Union: registration applications, clinical trials and application matters	Beijing Union	Beijing Union
COVID-19	Global (excluding (i) Russia and Ukraine and (ii) Brazil and other regions of South America)*	Our Company	Our Company	Our Company
	Russia and Ukraine	Beijing Union: registration applications, clinical trials and application matters	Beijing Union	Beijing Union
	Brazil and other regions of South America	Beijing Union, Brazil Agent and Brazil Agent Affiliate: registrations applications, clinical trials and application matters	Brazil Agent Affiliate	Brazil Agent Affiliate
Blood cancer	Global (excluding Russia and Ukraine)	Our Company	Our Company	Our Company
	Russia and Ukraine	Beijing Union: registration applications, clinical trials and application matters	Beijing Union	Beijing Union

Technology Transfer Agreement with the National Institute of Pathogen Biology, Chinese Academy of Medical Sciences

On January 1, 2023, we entered into a Technology Transfer Agreement with the National Institute of Pathogen Biology, Chinese Academy of Medical Sciences related to the transfer of technical secret of a broad-spectrum viral fusion inhibitor for purpose of developing a drug for the treatment of HIV infection, for which Henan Genuine has submitted two patent applications. We shall be entitled to the exclusive right to develop based on the technical secret and to manufacture and commercialize products. We shall also be entitled to the patent application and ownership relating to the technical secret globally, and the inventors shall be our designated personnel. The total consideration shall be RMB100 million, to be settled in five installments as follows: (i) RMB20 million within ten business days after the execution of the Technology Transfer Agreement, (ii) RMB20 million within ten business days after the IND approval for the first drug candidate under this project is obtained, (iii) RMB20 million within ten business days after the completion of the first Phase I clinical trial under this project, (iv) RMB20 million within ten business days after the completion of the first Phase II clinical trial under this project, and (v) RMB20 million within ten business days after the first NDA under this project is obtained.

As of the Latest Practicable Date, we were still in the early research stage of the potential drug candidates. We settled the first RMB20 million in 2023 according to the payment schedule as provided, and the remaining RMB80 million will be payable upon the achievement of milestones. We have settled and expect to settle the remaining portion using our working capital.

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Collaboration Agreement with Innovent

We have entered into a collaboration agreement with Innovent Biologics (Suzhou) Co., Ltd. (“**Innovent**”), a principal subsidiary of Innovent Biologics, Inc., a company listed on the Main Board of the Stock Exchange (01801.HK), under which Innovent has agreed to supply for nil consideration a sufficient quantity of SINTILIMAB (“**Innovent Compound**”), a commercialized anti-PD-1 agent owned by Innovent, for the Phase I clinical trial of azvudine + anti-PD-1 combination therapy for the treatment of cancer indications in accordance with the research and development plan approved by both parties. As the sponsor, we shall be responsible for conducting the clinical trial, while Innovent shall be granted access to the Phase I clinical data. Salient terms of the collaboration agreement are summarized as follows:

- *Cooperation Regions.* Chinese Mainland, Hong Kong and Macau.
- *Cooperation Scope of Indications.* Oncology.
- *Cooperation Product.* Azvudine + Innovent Compound.
- *Cooperation.* (1) Parties have agreed to collaborate on a Phase I clinical trial initiated by Henan Genuine to evaluate the safety, PK, PD, and preliminary efficacy of concurrent and/or sequential administration of the Innovent Compound and the azvudine in cancer patients, and to jointly explore combination therapies for the treatment or prevention in the field of immuno-oncology. (2) Innovent shall supply Innovent Compound, while Henan Genuine shall supply azvudine for the R&D activities of the azvudine + anti-PD-1 combination therapy. (3) Henan Genuine is the sponsor of the clinical trial, responsible for obtaining the necessary approvals and permits for this trial, including IND approval and approval from the ethics committee.
- *R&D Activities.* (1) Henan Genuine shall be responsible for formulating the R&D plan for Innovent’s review and approval. (2) Innovent has the right to immediately terminate the R&D plan and all related R&D activities upon written notification to Henan Genuine if any R&D activities conducted in accordance with this plan raise safety concerns. In case of such termination, Henan Genuine shall take commercially reasonable efforts to terminate the clinical trial and be responsible for the relevant costs and expenses. (3) Henan Genuine shall be solely responsible for the communications with the competent authorities. (4) Both parties have agreed to grant each other the right, free of charge, to use the clinical data derived from the clinical trial. Neither party may use the aforementioned data for the promotion or application of its own compound solely or for any other purpose beyond those stipulated in the agreement.
- *Development Costs.* Henan Genuine shall bear all costs and expenses related to any R&D activities and other activities required for the research. Innovent will support the research solely by providing Innovent Compound.
- *Intellectual and Proprietary Rights.* Under the collaboration, both parties shall maintain ownership of each party’s respective background intellectual property rights, and each party’s respective collaboration IP (being those know-how solely generated by or on behalf of this party and those know-how generated by or on behalf of this party that constitute an improvement or modification of its background IP). All right, title and interest in joint collaborative technologies, i.e. technologies jointly developed by both parties during the collaboration, shall be jointly owned by both parties.
- *Term and Termination.* The agreement shall be effective from the effective date until the final research report of the research under the agreement is delivered after the completion of the R&D plan, except for early termination as provided under the agreement. The agreement can be terminated for cause, including termination upon breach of contract and failure to cure the breach within 60 days of notice, and termination upon a party’s bankruptcy, liquidation, or bankruptcy receivership proceedings, or after the transfer of a substantial portion of assets in favor of a creditor. If all approved R&D plans have been terminated, and no alternative R&D plan is approved within 60 days, the agreement can be terminated.
- *Dispute Resolution.* The agreement is governed by PRC law. Any dispute shall be first resolved through amicable negotiations; if unresolved, such dispute shall be submitted to Shanghai International Economic and Trade Arbitration Commission for arbitration.

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In addition to the licensing and collaborations mentioned above, we constantly explore opportunities to collaborate with leading universities and research institutions in China to supplement our own R&D capabilities and support our drug development projects.

RESEARCH & DEVELOPMENT

We believe that R&D is crucial to our business growth and the success of our operations. For each drug candidate, we typically form a project team in charge of the whole development progress and managing the daily R&D work. The drug discovery process generally includes target identification, validation, hit identification, hit to lead and lead optimization, followed by preclinical and clinical studies to evaluate and confirm the functions, safety and efficacy of each drug candidate. We have established or are establishing various integrated R&D platforms to support our drug development from drug discovery to clinical trials. Our R&D activities have laid a solid foundation for future manufacturing and commercialization of our drug candidates.

In the past, the development of our Core Products and other drug candidates encountered certain delays, primarily due to inherent clinical trial uncertainties such as patient enrollment, protocol amendments and data review. As advised by Frost & Sullivan, such delays are commonly observed in the pharmaceutical industry and are in line with industry norms. We confirm these past delays have not adversely affected our business and financial status, as our core R&D direction remains unchanged, we keep making solid progress in drug R&D and registration, and we hold adequate cash for sustainable operation. However, we cannot assure you that our future R&D activities will not experience delays and, if any similar delays take place in the future, we cannot guarantee that our business operation and financial position will not be materially adversely impacted. See “Risk Factors—Risks Relating to the Development of Our Pipeline Products—A majority of our drug portfolio are currently in preclinical or clinical development, including our Core Products. If we are unable to successfully complete development, or experience significant delays in doing so, our business, financial condition, results of operations and prospects will be materially harmed.”

We have implemented the following measures to mitigate past delays and to minimize or address potential future delays:

- **Enhancement of R&D capabilities:** We have continuously expanded our R&D team, with a significant increase in clinical development personnel, and have strengthened our capabilities in clinical trial design, monitoring and operations to support the accelerated advancement of our pipeline projects.
- **Improvement of R&D project management system:** We have further refined our standardized R&D project management framework by implementing stage-gated milestone controls across all pipeline drugs, clearly defining key milestones and deliverables. Through regular project reviews and progress assessments, we aim to enhance execution efficiency and transparency.
- **Optimization of external collaboration model:** We have optimized our collaboration with qualified, leading CROs by outsourcing non-core functions such as sample testing and data entry, while retaining control over critical functions including trial design, medical decision-making, data verification and quality control, thereby ensuring the integrity and compliance of clinical trial data.
- **Strengthening clinical resource planning:** We have established long-term collaborations with leading tertiary hospitals and clinical research centers in China and secured investigator resources and clinical trial capacity in advance, which facilitates more efficient patient enrollment for our pipeline drugs.

Looking forward, we intend to implement the following measures to further manage and reduce the likelihood of similar delays:

- **Enhancement of performance evaluation and incentive mechanisms:** We plan to further align R&D project timelines with team performance evaluation and provide additional incentives for the early achievement of key milestones.

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- **Dynamic pipeline management:** We intend to adopt a more dynamic approach to pipeline management by regularly evaluating the clinical value, development progress and commercial potential of our pipeline candidates, prioritizing resources toward core projects and adjusting the development pace of non-core projects as appropriate to avoid resource dispersion and improve overall efficiency.

In-house R&D Activities

We have an in-house R&D management team composed of senior experts in the field of international drug research and development. Dr. Du Jinfa (杜錦發), the chairman of our Board, executive Director, chief executive officer, chief scientific officer of our Company, recognized as “State Specially Recruited Experts (國家特聘專家)” by the PRC government, is one of the inventors of sofosbuvir, drug for treating hepatitis C which won the 2014 Prix Galien Award. He is also one of the inventors of azvudine (for the treatment of COVID-19), CL-197 and dosimertinib, our Core Products. *Cell* has commented that sofosbuvir is one of the most significant public health accomplishments of our generation. Our senior management personnel, such as Dr. Dang Qun, Dr. Guo Chang Yue and Dr. Li Pan, all have served in internationally-renowned biomedical companies and has an average of nearly 30 years of extensive experience in the fields of innovative drug research and development, translational medicine, and clinical trial management, which has laid a solid foundation for our continuous innovation and global competitiveness in the field of biomedicine. For more details on the expertise and experience of our senior management, please see “Directors and Senior Management”.

In addition to our senior management team, we also have nine other key R&D personnel who hold a master or doctoral degree and are backed with profound experience in the industry. Each of our key R&D personnel has been designated with responsibilities in accordance with their expertise. For instance, Dr. Guo Na, who was a doctor at the infection center of the largest research center for our Phase II clinical trials of azvudine for HIV infections and thus participated in the Phase II trial, officially joined our Group in March 2022 and is the person in charge of the HIV Phase III clinical trial and the CL-197 Phase IIa clinical trial. Dr. Qin Zhiyong, Ms. Jia Limin, Ms. Ma Haoling and Dr. Li Yaozong and Ms. Hu Dongmei conducted the preclinical studies and/or clinical trials for the drug candidates in our pipeline, while Ms. He Jinxiu has been generally in charge of registration and application matters. Dr. Chen Lei and Dr. Guo Xiaoqi are in charge of the preclinical studies of earlier staged programs including the discovery of ADC drugs for monoclonal antibody targeting prostate-specific membrane antigen.

Our key R&D personnel have been extensively involved in the R&D for our Core Products and other drug candidates in our pipeline. Leveraging our extensive experience in drug research and development, we have established a comprehensive research and development platform, including a highly selective novel nucleoside broad-spectrum anti-tumor drug R&D platform, a TOPO1 inhibitor and XDC drug R&D platform, a drug target discovery and validation platform, and an innovative drug design and optimization platform. These platforms cover the entire drug development process, from early target screening to preclinical research, to clinical trials and subsequent optimization, providing strong technical support and systematic safeguards to accelerate the discovery and development of innovative drugs.

Despite certain changes in the composition of the R&D team since the development of our Core Product, especially that a majority of the personnel key to our R&D team and development of our Core Products did not remain employed as of the Latest Practicable Date due to personal reasons, we believe that our in-house R&D capabilities remain independent and sufficient, and have not been adversely affected. Such changes primarily involved personnel engaged in preclinical and early-stage clinical development, while our core R&D team has remained largely stable, particularly since the commencement of Phase III clinical trials of azvudine. Our retained core R&D personnel possess extensive experience in clinical development, and we have continued to advance our pipeline, including completion of multiple clinical trials and progress in IND approvals and applications for various indications. In addition, appropriate handover arrangements were implemented prior to the departure of relevant personnel to ensure continuity of our R&D functions. As a result, such personnel changes have not affected our R&D capabilities or the development progress of our Core Product.

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As of December 31, 2025, our in-house R&D team consisted of 77 members with experience in the biotech and pharmaceutical industries, among whom 41 hold a master's degree and nine hold a doctoral degree. We have adopted standard operating procedures that govern each stage of our drug development process.

Our Platforms

To support our internal R&D activities, we have established multiple R&D platforms, including (i) a highly selective novel nucleoside broad-spectrum anti-tumor drug R&D platform, (ii) a TOPO1 inhibitor and XDC drug R&D platform especially targeting tumors resistant to current ADCs, (iii) a drug target discovery and validation platform, and (iv) an innovative drug design and optimization platform.

Highly selective novel nucleoside broad-spectrum anti-tumor drug research and development platform

Since nucleoside drugs have different mechanisms of action compared with non-nucleoside chemotherapy drugs and various targeted drugs, combination therapy of azvudine with numerous non-nucleoside chemotherapy drugs or targeted drugs may produce synergistic effects. Based on our observation that azvudine upregulated CD4⁺ T cells, CD8⁺ T cells, and NK cells in the tumor microenvironment by downregulating MDSC expression, we have established a platform focused on the discovery of other highly selective novel nucleoside broad-spectrum anti-tumor drugs. These inhibitors are designed to block the recruitment, differentiation, activation or function of MDSC, reduce their inhibitory effects on immune cells, and restore the body's normal immune surveillance and anti-tumor immune function. We will also explore the combination therapies with the novel nucleosides developed from platform with other targeted therapies or immunomodulatory drugs or chemotherapies to improve clinical benefits. Through combined use, not only can the immunosuppressive activity of MDSC be directly inhibited, but the anti-tumor effect of other treatments can also be enhanced, reducing the risk of tumor recurrence and prolonging patient survival.

TOPO1 inhibitors and XDC drug development platform

Over the past few decades, the most widely used TOPO1 inhibitor has been irinotecan, a camptothecin derivative, which has become the backbone of various anti-tumor combination therapies. However, camptothecin-based drugs face the problems of primary and post-treatment drug resistance, which is a shared challenge faced by the industry. Through AI-computer-aided design and by changing the structure of the parent nucleus, we have discovered hundreds of novel TOPO1 inhibitor molecules with new structures, and have discovered multiple candidate compounds with the properties of a new generation of payloads. Our TOPO1 inhibitor R&D platform can establish extensive external collaborations, thereby effectively developing many new tumor treatment drug candidates. Based on this, we are developing key components of conjugate drugs such as ADC, PDC, SMDC, etc. on this platform. We will develop a series of innovative drugs through the XDC platform, especially a series of effective drugs for existing TOPO1 inhibitors and their ADCs and other drug-resistant tumors, providing new solutions for unmet medical needs.

Drug target discovery and validation platform

We have constructed dozens of *in vitro* cell line models, covering a variety of solid tumors and blood cancer. At the same time, we have also established a set of *in vivo* model systems, including dozens of cell-derived xenograft (CDX) models, human tumor xenograft (PDX) models, and Syngeneic models. The CDX model can quickly evaluate the anti-tumor effect of drugs *in vivo* by transplanting tumor cell lines into immunodeficient mice; the PDX mode uses patient-derived tumor tissue transplantation to better preserve the heterogeneity and microenvironment characteristics of the tumor; the Syngeneic model uses a syngeneic mouse tumor model with a complete immune system, which can more realistically reflect the interaction between the tumor and the body's immune system, and provides an important tool for studying the efficacy and mechanism of immunotherapy drugs.

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Innovative drug design and optimization platform

Based on the in-depth understanding of the target structure and function, computer-aided drug design technology is used, combined with virtual screening, molecular docking and molecular dynamics simulation methods, to design lead compounds with high activity, high selectivity and good pharmacokinetic properties. By structurally modifying and optimizing the lead compounds, the binding affinity, stability and specificity with the target are continuously improved, the potential toxic side effects are reduced, and the druggability of the drug is improved. A complete drug activity evaluation system is established with stages including *in vitro* enzyme activity determination, cell-level functional experiments, *in vivo* efficacy evaluation of animal models, and pharmacokinetic and safety evaluation. Through systematic experimental research and data analysis, candidate drugs with clinical application potential are quickly screened, and in-depth mechanism research and preclinical development are carried out on them.

Outsourced R&D Activities

In line with common industry practice, we typically engage CROs to conduct preclinical studies and then collaborate with physicians in local hospitals to conduct clinical trials, which are done primarily by engaging NMPA-certified clinical centers and CROs who meet our requirements. We select our CROs based on various factors, including their GCP certificates, clinical trial experience, professional experience of their team members and proposed budgets. Our clinical trial management team is responsible for managing the overall clinical trial process for our drug candidates, making key decisions regarding the overall development direction and overseeing CROs' work. The involvement and roles of CROs in the development of novel molecule drug candidates are typically standardized and similar among different projects. The work scope of these third parties in the development of our drug candidates may have slight variation, subject to our overall management and instructions. The CROs we engaged are primarily responsible for preparing clinical trial plans, reviewing the clinical trial data, handling and managing transactional matters at the trial sites and performing other supporting duties in relation to our clinical trials. We review plans related to clinical trials proposed by CROs and provide our feedback to CROs on these draft plans. After revisions, we approve the final plans to be used for the clinical trials. We hold regular progress meetings with our CROs to ensure that the trials are on track. We review documentations prepared by our CROs and follow up with them if we have any questions on the documentation. Our CROs are also required to fully cooperate with our monitoring and inspection activities and rectify any issue identified during such inspections.

Key terms of the agreement with our CROs are summarized as follows:

- *Service.* The CROs provide clinical trial services, including project management, investigative site management, monitoring, data management and lab services for clinical studies.
- *Term.* The CROs are required to complete relevant clinical trial projects set out in the agreement within the prescribed time limit.
- *Payment.* We are required to make either full payment or payments in installments according to the prescribed payment schedule.
- *Intellectual property rights.* All intellectual property rights arising from the clinical trial process for our drug candidates belong to us. The CROs are required to maintain confidentiality as agreed.
- *Regulatory compliance.* We require our CROs to comply with all laws, regulations and mandatory industry standards.

For the years ended December 31, 2024 and 2025, we engaged 19 and 25 CROs, respectively, to assist the R&D of our drug candidates. All the CROs engaged during the Track Record Period are Independent Third Parties. The service fees we paid to our CROs during the Track Record Period were determined on a case-by-case basis with regard to the scale of the relevant clinical trials (primarily depending on the number of enrolled patients, trial sites and follow-up visits) and the service scope.

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REGULATORY REGISTRATION

After successful completion of a registrational clinical trial, we apply for approval from the NMPA or other relevant authorities to register our drug candidates. For each drug candidate, we are required to file the registration application in accordance with the relevant registration regulations. The registration process may be time-consuming, and we believe our employees' extensive experience in managing the registration process will be critical for our commercial success.

COMMERCIALIZATION

Substantially all of our revenue in 2024 was generated from the Fosun Pharma Agreements, under which we sold azvudine through the sales channels of Fosun Pharmaceutical Industrial. During the Track Record Period and prior to the termination of collaboration with Fosun Pharmaceutical Industrial in September 2024, Fosun Pharmaceutical Industrial was our only distributor. See “—Our Technology Transfer Arrangements and Collaborations—Fosun Pharma Strategic Cooperation Agreements” for details. After the termination of collaboration with Fosun Pharmaceutical Industrial in September 2024, we engaged offline and online distributors as well as CSOs to promote the sales of our commercialized product, azvudine.

We have formulated detailed commercialization strategies for our commercialized product, azvudine, and our drug candidates. We have also formed, and will continue to expand, our own commercialization team to fully realize the value of our products.

Commercialization Strategies

We have adopted an on-line/off-line omni-channel and strategic academic sales model to promote and distribute our products, including azvudine, which is already commercialized, as well as future products to be launched in the market. We will quickly establish an integrated commercialization system. Through marketing, market access, digital marketing, medical value exploration, direct-sales, recruitment of distributors and commercial excellence, we will continue to deliver accurate and up-to-date academic information with clinical value to the market to promote our products.

We are confident in azvudine's prospects in both the COVID-19 and HIV markets and have a proactive and sustainable commercialization goal. In the COVID-19 treatment field, we are closely following the trends in pathogen identification, rapidly increasing the drug's omnichannel coverage, and establishing deep partnerships with leading distributors, e-commerce platforms, and CSOs. Through coordinated online and offline coverage, we aim to respond to the uncertainties of the pandemic and maximize product accessibility.

Based on the National Center for Disease Control and Prevention's report, there were approximately 1.054 million COVID-19 patients in the first half of 2025. Azvudine achieved a COVID-19 patient market share of approximately 19%, maintaining its leading position in the domestic market (where seven effective COVID-19 drugs have already been launched), with a further increase from its 2024 market share.

In the HIV treatment landscape, China has an estimated 1.4 million people living with HIV, with approximately 100,000 new diagnoses each year. Among the 1.4 million existing patients, 10% to 40% are INRs, representing a large patient population with no effective treatment options. Azvudine not only can be used for the treatment of general population of HIV patients, but also has the potential to be used for treating INRs, demonstrating critical unmet medical needs and thus serves as the driver of our growth in the HIV sector. Strategically, against the backdrop of the evolving COVID-19 epidemiological trend and the highly competitive HIV treatment landscape, we have shifted the commercialization focus of azvudine to the HIV field and identified its significant potential in the treatment of INRs in HIV-infected patients, a patient group with substantial unmet clinical needs. We believe that azvudine's demonstrated potential in addressing this gap is expected to create substantial growth opportunities for its global commercialization and drive a pivotal turnaround in its market performance. Since obtaining access to an HIV patient management program in 2025, we expect data visibility to improve and, as the relevant clinical potential of azvudine is progressively realized, anticipate substantial growth in its sales.

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We expect to continue to promote the sales of azvudine and accumulate HIV patients using azvudine. This will further solidify azvudine's market share in COVID-19 treatment and rapidly enhance its academic and brand influence in the HIV market, and a key factor contributing to our profitability from the commercialization of azvudine. We have already implemented our established business plan in 2025, and we will continue to implement the following core initiatives:

1. Building an Omnichannel Academic System: (1) established partnerships with authoritative academic platforms and continuously deliver the differentiated clinical value of azvudine; (2) initiate experts consensus or treatment guideline updates to promote the continuous inclusion of azvudine in national recommended treatment regimens for infectious/respiratory diseases, thereby enhancing its clinical acceptance; (3) further strengthen our network of academicians and KOLs, inviting authoritative experts to present the latest research data on azvudine at top domestic and international academic conferences to enhance our international and domestic influence; (4) establish an "Azvudine Expert Advisory Committee" composed of 10 to 15 top national infectious disease/respiratory specialists, holding two closed-door seminars annually to optimize the product's clinical positioning; (5) continue to accumulate high-quality clinical data on azvudine and promote high-quality real-world studies and evidence-based medicine; and (6) attended and expect to attend more academic events to promote the influence of azvudine.
2. Constructing an integrated communication system and strengthening patient education: (1) continuously convey the latest treatment concepts and drug application knowledge to patients and medical professionals; (2) regularly publish detailed drug treatment guidelines, patient case analyses, and expert interpretations to help patients and doctors make the most suitable treatment decisions; (3) better meet the needs of patients and medical professionals, enhance the market competitiveness of drugs, and ensure the efficient promotion and widespread application of COVID-19 drugs in a complex and ever-changing market environment; and (4) continue to build an integrated communication system, including collaborations with self-media, industry media, and influencer doctors.
3. Establish inhouse sales force and leverage resources of distributors and CSOs. See below "—Commercialization Team," "—Business management system," "—Marketing Management System," "—Offline Distributor Management System," "—Online Distributor Management System," and "—CSO Management System" for details.

Commercialization Team

Talents are the cornerstone of our commercialization development. We have established a professional and well-functioning commercialization team, consisting of 28 members as of the Latest Practicable Date, for the commercialization of azvudine, and for laying a good foundation for the commercialization of the our drug candidates to be launched in the market.

The key functions of our commercialization team include: formulating annual business plan of our products based on, among others, feedbacks from the market and customers, information of competing products and our sales team; establishing and maintaining a communication matrix for dissemination of product information to the market, especially to physicians and patients; collecting, analyzing and processing data from commercialization activities, identifying potential opportunities and issues and providing feasible proposals and solutions to improve the performance of commercialization team overall; recruiting and managing CSOs; direct sales in key provinces and cities; and development and maintenance of online and offline distributors.

With the growth of our business, we expect to expand the commercialization team to approximately 100 personnel within two years to support our product promotion in medical institutions in China.

Business Management System

In developing our business management system, we have focused on the following core dimensions to ensure the efficient operation and sustainable growth of the Company:

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- Distributor development: We have formulated a comprehensive and attractive policy to develop distributors, aiming to attract high-quality business partners to join our distribution network.
- Compliance management: Our compliance management features three aspects, namely training, inspection and review.

In summary, our business management system has laid a solid foundation for the steady development of the enterprise through refined management and innovative strategies.

Marketing Management System

In developing our marketing system, we have followed a rigorous and innovative set of dimensions designed to ensure the efficiency, compliance and continuous growth of corporate marketing activities. The following are the core components of our marketing system:

- Compliance criteria: We have established strict compliance criteria to ensure that all marketing activities comply with relevant laws, regulations and industry norms.
- Promotion criteria: We have established clear promotion criteria to guide the design and execution of our marketing campaigns. These criteria emphasize the precise positioning of target markets, deepen the understanding of customers' needs and demonstrate our differentiated competitive advantages to ensure that promotional activities are able to effectively attract potential customers and enhance brand awareness.

In conclusion, our marketing system has provided a strong assurance for the steady development of our enterprise through rigorous compliance, innovative and effective management strategies.

Offline Distributor Management System

As we undergo the in-depth market-mapping and rapid expansion of azvudine in the Chinese market, we are acutely aware of the strategic importance of the distributor network. At present, we have covered an aggregate of more than 50,000 medical institutions in 31 provinces and municipalities across the country, serving not only as a bridge between the products and the market, but also as the cornerstone of achieving broad market coverage and efficient supply. In order to achieve long-term development of distributors, we have established a set of efficient tier 1 distributor development and management mechanisms. We had entered into distribution agreements with 49 and 81 offline distributors as of December 31, 2024 and 2025, respectively.

Distributor development strategy

Under the principle of “selecting and cooperating to create a win-win situation,” we have actively sought and engaged a group of distributors with strong distribution capabilities, profound industrial resources and excellent service quality. Through a rigorous qualification review, process market research and a comprehensive assessment, we have ensured that each of our distributors has the capability and potential to accurately deliver azvudine to various medical terminals.

Distributor management system

To ensure the efficient operation and compliance management of our distributor network, we have established a comprehensive management system. Through signing a detailed cooperation agreement, we have clearly defined the rights and obligations of both parties, including key terms such as sales targets, market strategies, inventory management and after-sales service, which has laid a solid foundation for long-term cooperation. At the same time, we have set up a dedicated distributor management team to communicate and provide trainings to distributors on a regular basis to enhance their business capabilities and compliance awareness.

Meanwhile, based on the updated strategies, we and Fosun Pharmaceutical entered into an amended agreement in September 2024 to terminate the former license of commercialization right of azvudine in China. See “—Our Technology Transfer Arrangements and Collaborations—Fosun

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Pharma Strategic Cooperation Agreements” for details. The termination of collaboration clearly reflects that we have recovered the exclusive commercialization right of azvudine in Chinese Mainland from Fosun Pharmaceutical Industrial.

Based on such a set of scientific and efficient distributor development and management mechanism, azvudine has been able to continue to cover an enough number of medical institutions in the Chinese market, laying a solid foundation for sustainable sales and steady increase in market share of the product. Looking forward, we will continue to optimize this system and deepen the cooperation with distributors to jointly create a broader market space and provide Chinese and global patients with more convenient medical and healthcare services with a higher quality.

Online Distributor Management System

The sales of pharmaceutical products on e-commerce platforms in China are advantageous in many aspects including convenience, price transparency, quality service and policy support. These advantages promote the rapid development of the pharmaceutical e-commerce industry and provide consumers with a more convenient, efficient and safe pharmaceutical shopping experience. In such an open, high-potential and competitive online market environment of China, we recognize the key role of an online distributor network in driving sales growth and enhancing brand awareness of azvudine. As an integral part of our core strategy, online marketing is leading our transformation to digital and intelligent marketing. We had entered into distribution agreements with four and ten online distributors as of December 31, 2024 and 2025, respectively.

E-commerce development strategy

Leveraging our keen insight and deep understanding of market trends, we focus on in-depth layout and strategy development of top e-commerce platforms in China. Our e-commerce team sports in-depth industry knowledge and practical experience, enabling us to accurately capture market opportunities and quickly respond to consumer needs. Through careful planning and active communication, we have successfully entered into cooperation arrangements with several leading e-commerce platforms in China to jointly establish an online sales channel for azvudine and have successfully achieved sales. These platforms have a large user base and an efficient logistics system, providing a broad space of visibility and convenient shopping channels for our products.

E-commerce management system

To ensure the healthy operation and efficient synergy of our online channels, we have established an efficient management system. Through signing a detailed cooperation agreement, we have clarified the cooperation scope, sales targets, marketing strategies and after-sales service standards for both parties, which has laid a solid foundation for long-term cooperation.

Looking forward, we will continue deepening our cooperation with various major e-commerce platforms, optimizing our online networks continuously and explore more innovative marketing models, so as to provide consumers in the market of China with more convenient, efficient and high-quality medical and healthcare services, so as to jointly promote online sales of azvudine and future products to be launched in the market reaching new heights.

Distribution Agreements

We typically enter into distribution agreements which are sales and purchase agreements in nature. The salient terms typically include the name, quantity and price of the product to be distributed, location of delivery, payment arrangements, and other terms as agreed upon by the parties. We believe that the agreements are fair and in-line with common practices of the industry. We generally do not accept returns of products from sales to distributors, except for particular circumstances as agreed with the distributors, such as where the products have a shorter durability period than agreed and product quality defects. As of December 31, 2025, our distributors had returned 23,777 boxes of azvudine, representing approximately 16.3% of the number of azvudine contributing to our revenue in 2025, as we terminated the business relationship with one distributor.

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CSO Management System

In constructing and expanding our marketing ecosystem, the introduction and management of contract sales organizations (CSOs) play a crucial role. We are well aware that an efficient and professional CSO management system is a key factor to ensure accurate implementation of market strategies and enhancement of brand influence and market share. Therefore, we have established a set of comprehensive and scientific CSO management system, aiming at recruiting and nurturing a professional team who have deep understanding of market demand and implement market strategies efficiently. We engaged 17 and 21 CSOs as of December 31, 2024 and December 31, 2025, respectively.

Assessment and recruitment of high-quality promotion service providers

We have formulated strict CSO evaluation and recruitment criteria to ensure that each partner has excellent professional capabilities, extensive market experience and good reputation in the industry. Through considering multiple aspects, including but not limited to past performance, team strength, market insight and compliance performance, we have carefully selected high-quality CSOs that can grow together with us. In addition, we have also established a long-term partnership evaluation mechanism to regularly review and adjust our cooperation strategies to ensure that the CSO team remains highly aligned with our market goals.

Implementation of market strategies

To ensure the effective implementation of our market strategies, we work closely with our CSO team to formulate detailed marketing plans and the implementation plans. Through regular meetings, strategy seminars and implementation feedback mechanism, we ensure that the market strategies will be accurately communicated to the CSO team, and continuously optimized and adjusted in actual implementation. Meanwhile, we use advanced digital tools and data analysis technologies to conduct real-time monitoring and result evaluation of marketing activities, aiming at ensuring that every cent of investment will be able to bring maximum market returns.

Training for personnel of promotion service providers

We are acutely aware that the professional ability and service quality of the CSO team are directly related to the effectiveness of marketing. Therefore, we have established a comprehensive training system for CSO personnels, which covers various aspects, including market trend analysis, popularization of product knowledge, improvement of sales skills and compliance education. Through a combination of online and offline training methods, we continue to improve the professionalism and service quality of our CSO team to ensure that they can face market challenges with the most professional attitude and provide customers with excellent service experience.

Salient terms of CSO service agreements

We generally enter into service agreements with a term of one year, renewable upon written agreement between both parties. Our CSOs are generally assigned with a specific region, which may range from a district to several cities or a province, as provided by the service agreement to conduct promotion and marketing activities for azvudine, which may include visiting hospitals and stores, collecting feedbacks and market information, holding academic seminars and conducting surveys with end users. A CSO can produce marketing materials by using our brand name, name and trademarks of our products, but shall not present itself as our agent. A CSO shall comply with all applicable laws and regulation when performing its obligations under the service agreement.

We generally settle payments with our CSO monthly, based on the actual costs incurred in the promotion and marketing activities plus service fees. CSOs shall submit invoices of costs and supporting documents for the relevant marketing materials or events within a period of time (e.g. 10 days) after month-end, and we shall make payments within a period of time (e.g. 10 days) after both parties confirm on the amount of payment.

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Measures to prevent cannibalization amongst various sales channels

We have adopted measures to prevent cannibalization amongst various sales channels as follows:

- Online channels: We currently collaborate with leading domestic e-commerce platforms. These platforms handle overall online sales through their internet hospital platforms, avoiding conflict with offline channels. Online sales focus on self-paying patients, achieving compliant sales through the circulation of electronic prescriptions from internet hospitals. Furthermore, the company has established a management mechanism to monitor the retail prices on all e-commerce platforms, ensuring relative price stability.
- Offline channels: (i) each distributor shall cover a designated region as agreed in the distribution agreement, (ii) we adopt a drug traceability code system to monitor the flow of goods in real time, and any cross-region selling behavior will trigger a penalty under the distribution agreement; (iii) our inhouse sales team cover Beijing, Tianjin and Henan markets, while our distributors cover other regions in Chinese Mainland.

Pricing

With regard to the intensive competition in the pharmaceutical industry, we are fully aware that product price management is not only a reflection of corporate profitability, but also an integrated demonstration of social responsibility and patient well-being. The price of our product is most favorable among similar products to ensure that patients may access high-quality medical service at a reasonable price. In this context, our Core Product, azvudine tablets, has achieved remarkable results in terms of price management and market positioning.

Competitive Price due to Inclusion in the NRDL

In April 2023, azvudine was officially included in the NRDL, providing a more economical and effective treatment option for patients. The price of azvudine was lowered from RMB270 per box to RMB174.65 per box after the inclusion to the NRDL. Our core considerations behind the inclusion to the NRDL and reduced sales price are (i) to respond to the national call, reduce patient expenses, and benefit a vast number of patients to confront with the major public health event of the COVID-19 pandemic; and (ii) to ensure azvudine is accessible for more patients leveraging the nationwide coverage of NRDL network. We view the inclusion of azvudine in the NRDL a crucial step in the market access, as the vast majority of drugs prescribed in public hospitals in China are covered by the NRDL, leaving non-NRDL drugs facing strict restrictions on market access. Inclusion in the NRDL helps reduce patients' costs and greatly improves drug accessibility, facilitating the rapid expansion of azvudine's coverage. Despite the lowered price of azvudine after inclusion in the NRDL, the inclusion has helped azvudine avoid requirements for further price reductions, thereby maintaining price stability. In the COVID-19 therapeutic area, apart from one imported peer drug, the domestic peer drugs of azvudine have all been included in the NRDL. In the HIV therapeutic area, a majority of the commonly used anti-HIV drugs have been included in the NRDL.

After entering the China Healthcare Security ("CHS") system, we are fully aware of the importance of maintaining product price stability. During the 2024 NRDL negotiations, leveraging its superior product quality and proactive market strategies, azvudine successfully remained included in the NRDL with the coverage and price paid for our products unchanged. This achievement not only demonstrates our in-depth understanding and positive response to the national health insurance policy, but also demonstrates our prudent and forward-looking pricing management. Through stable payment scope and prices, we ensure that patients can continue to receive high-quality treatment options at reasonable costs, thereby improving patients' medication compliance and treatment outcomes.

More importantly, according to the terms of the NRDL negotiations, products with unchanged payment scope and payment price during two consecutive negotiation periods will be included in the routine catalogue of the NRDL. This policy arrangement provides a solid assurance for the future price stability of our products. Therefore, before the emergence of generic versions of azvudine in China market, the medical insurance reimbursement price of azvudine will remain very

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stable. The price of our products paid by the CHS has an advantage in the market, which not only reduces the cost of the state but also greatly improves the accessibility of drugs for patients, making them more affordable and available to more people who can benefit from this innovative therapy. Going forward, we will continue to uphold our “patient-centric” value and optimize our product price management strategy.

No Adverse Impact by Potential Preferential Tax Treatment of Imported Drugs

On March 29, 2021, the Ministry of Finance, the General Administration of Customs and the STA jointly issued a circular detailing the preferential tax treatment for importing anti-HIV/AIDS drugs. From January 1, 2021 to December 31, 2030, anti-HIV/AIDS drugs imported upon the entrustment of the National Health Commission are exempt from customs duties and import VAT. The National Health Commission shall determine the list of anti-HIV/AIDS drugs and entrusted import entities eligible for the tax exemption policy and report this to the Ministry of Finance, the General Administration of Customs and the STA. Based on a verbal consultation with the National Health Commission and a public search by our PRC Legal Advisors, as of the Latest Practicable Date, the National Health Commission had not publicly released a specific list of eligible imported anti-HIV/AIDS drugs and entrusted import entities under the aforementioned tax exemption policy, and the extent of such tax exemption remained unclear. We do not believe the aforementioned tax exemption policy, once issued with more details, would have material adverse impacts on our business operations and financial conditions, given such preferential tax treatment, which typically include import customs duties and import VAT, will only reduce the prices of imported drugs by 2% to 6%. We consider such marginal cost reduction insufficient to offset the inherent pricing advantages of azvudine.

Global market expansion

As a major medical challenge after the COVID-19 pandemic, long COVID is attracting increasing attention from the global medical community. With respect to the broader global market, we have communicated with prospective partners to discuss the introduction of azvudine into the field of global long COVID therapy to provide patients with a new treatment option. We hope that through cooperation with the world’s leading medical institutions, azvudine and our other drug candidates can enter the international market sooner, bringing good news to patients around the world.

INHOUSE MANUFACTURING

Efficient and stable production and supply capabilities are critical to ensuring sustainable development and market competitiveness of enterprises. We have built a complete industrial chain from raw material procurement to output of finished product, fully demonstrating our production and supply capabilities and laying a solid foundation for our long-term stable growth.

As the core of our pharmaceutical business, our inhouse manufacturing facilities located in Pingdingshan, Henan are equipped with industry-leading manufacturing equipment and technologies, which comprehensively cover the entire manufacturing cycle, including granulation, drying, mixing, tablet compressing, primary packaging, secondary packaging and quality inspection. This all-round and integrated production capacity ensures the stability and consistency of product quality, greatly improves production efficiency and shortens the product launch cycle. Our annual production capacity is approximately three billion tablets, which not only satisfies the current market demand, but also reserves sufficient space for future market expansion.

We began construction of our production base in April 2019 and completed it in November 2019. We commenced the construction of three production lines in 2022 and completed between 2022 and 2023, with a combined annual production capacity of approximately 3 billion tablets. The utilization rate of the three production lines was approximately 0.4% in 2024 and 0.2% in 2025. The low utilization rate was caused by the change of market condition. We arrange production according to orders from sales. With the ease of the COVID-19 pandemic and the normalization of national pandemic control, sales of azvudine have decreased significantly, resulting in lower market demand and consequently, lower capacity utilization.

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In terms of quality control, our production base follows the relevant laws and regulations and standards of the NMPA, and has successfully passed the GMP compliance inspection for pharmaceutical products in May 2022. This certification is not only a high recognition of our production process and product quality, but also a firm guarantee for our continuous commitment to improving production management standards and ensuring the safety of patients' medication. We will continue to optimize our production process and improve our management level, so as to make more contributions to the sustainable and healthy development of the pharmaceutical industry.

CONTRACT MANUFACTURING

During the Track Record Period, we engaged seven drug manufacturers (“CMOs”) in China, all of which are Independent Third Parties, to manufacture azvudine. We engaged CMOs primarily for the following two reasons: (i) prior to obtaining the drug manufacturing license on April 21, 2022 and the receipt of the GMP inspection result notification on May 26, 2022, we were unable to conduct drug production activities. Therefore, we engaged two CMOs, both of which are reputable qualified pharmaceutical manufacturers, with the expectation of increasing market demand for azvudine after its approval; and (ii) after azvudine was approved for COVID-19 indication on July 25, 2022, in accordance with the requirements of the National Joint Prevention and Control Medical Material Security Group, and to implement the national policy requirements for precise prevention and control and ensure the market supply of azvudine tablets for the treatment of COVID-19, we engaged another five CMOs, all of which are reputable qualified pharmaceutical manufacturers. After February 2023 when our own production facilities were completed and sufficient to cover product demand, we did not outsource manufacturing to the CMOs, and subsequently terminated the cooperation with five of the collaborating CMOs as of December 31, 2025. As a result, we did not incur any cost of CMO service fees in 2024 and 2025.

Under our manufacturing framework agreement with our CMOs, we purchase the API for azvudine and provide formulation, technology and other documentation to them as required for manufacturing. Our CMOs are primarily responsible for manufacturing azvudine in finished dosage form pursuant to such formulation and technology as well as GMP certification requirements. Under the agreement, we are the sole owner of any proprietary rights to azvudine, including the right to market and sell azvudine after obtaining the NMPA approval.

We have also adopted procedures to ensure that the production qualifications, facilities and processes of our CMOs comply with applicable regulatory requirements and our internal guidelines. For example, we ensure that our CMOs have the requisite qualifications to carry out the manufacturing activities and our CMOs shall make appropriate adjustments with respect to any particular issue identified. During the Track Record Period, we did not experience any product quality issues with respect to azvudine manufactured by our CMOs.

SUPPLIERS

Our suppliers primarily include raw material suppliers, research and development service providers and owners of our rental properties. Our purchases from our five largest suppliers in 2024 and 2025 were RMB84.5 million and RMB23.9 million, respectively, accounting for approximately 40.1% and 17.7%, respectively, of our total purchases for the respective years. In the same years, purchases from our largest supplier were RMB40.8 million and RMB6.7 million, respectively, accounting for approximately 19.4% and 4.9%, respectively, of our total purchases for the respective years. All of our five largest suppliers during the Track Record Period were Independent Third Parties. None of our Directors, their associates or any of our current Shareholders (who, to the knowledge of our Directors, own more than 5% of our share capital) has any interest in any of our five largest suppliers that are required to be disclosed under the Listing Rules.

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The tables below summarize the purchases from our five largest suppliers for the periods indicated:

Five Largest Suppliers in 2024	Lengths of Business Relationship	Purchases	Purchase Amount	Percentage of Total Purchases
			RMB'000	%
Supplier A ⁽¹⁾	2019 to present	Intellectual property	40,777	19.4
Supplier B ⁽²⁾	2023 to present	Preclinical and clinical CRO services	24,430	11.6
Supplier C ⁽³⁾	2014 to present	Preclinical and clinical CRO services	9,108	4.3
Hainan Giantstar Technology Group Co., Ltd. (海南星捷安科技集團股份有限公司)	2023 to present	Preclinical and clinical CRO services	5,660	2.7
Supplier D ⁽⁴⁾	2023 to present	Preclinical and clinical CRO services	4,484	2.1

Five Largest Suppliers in 2025	Lengths of Business Relationship	Purchases	Purchased Amount	Percentage of Total Purchases
			RMB'000	%
Supplier B ⁽²⁾	2023 to present	Preclinical and clinical CRO services	6,650	4.9
Supplier E ⁽⁵⁾	2023 to present	Preclinical and clinical CRO services	4,819	3.6
Supplier F ⁽⁶⁾	2025 to present	Construction services	4,419	3.3
Supplier C ⁽³⁾	2014 to present	Preclinical and clinical CRO services	4,301	3.2
Supplier D ⁽⁴⁾	2023 to present	Preclinical and clinical CRO services	3,685	2.7

Notes:

- (1) Supplier A is a public university in Henan province.
- (2) Supplier B is a private company based in Tianjin, primarily engaging in providing CRO and medical research services. Its parent company is listed on the Hong Kong Stock Exchange and Shenzhen Stock Exchange.
- (3) Supplier C is a private company based in Tianjin, primarily engaging in providing preclinical and clinical CRO services. Its parent company is listed on the Hong Kong Stock Exchange and Shenzhen Stock Exchange.
- (4) Supplier D is a private company based in Shanghai, primarily engaging in providing preclinical and clinical CRO services. Its parent company is listed on the Hong Kong Stock Exchange and Shanghai Stock Exchange.

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- (5) Supplier E is a private company based in Shanghai, primarily engaging in providing preclinical and clinical CRO services.
- (6) Supplier F is a private company based in Henan province, primarily engaging in providing building construction, decoration and renovation services.

Our five largest suppliers generally grant us credit terms ranging from 5 days to 90 days, and payment to our suppliers are typically settled by wire transfer.

CUSTOMERS

During the Track Record Period, we primarily sold azvudine to Fosun Pharmaceutical Industrial in accordance with the Fosun Pharma Agreements after azvudine was approved for marketing in China. Our collaboration with Fosun Pharmaceutical Industrial began in 2022. In 2024, our five largest customers accounted for 99.6% of our total revenue, among which Fosun Pharmaceutical Industrial accounted for 99.2% with an aggregate sales of RMB235.9 million. Other than Fosun Pharmaceutical Industrial, our other five largest customers in 2024, being our distributors primarily engaged in sales of pharmaceutical products, in aggregate contributed to approximately 0.4% of our total revenue or approximately RMB1.1 million in sales, and individually, accounted for not more than 0.2% of our total revenue or not more than RMB0.5 million in sales. Considering the evolving market conditions and in the best interest of both parties, we entered into the Amendment Agreement with Fosun Pharmaceutical Industrial in September 2024, regaining the commercialization right under the Fosun Pharma Agreements. See “—Our Technology Transfer Arrangements and Collaborations—Fosun Pharma Strategic Cooperation Agreement” for details. We had entered into distribution agreements with 91 distributors, who are our customers, as of the December 31, 2025.

In 2025, our sales to our five largest customers was RMB18.0 million, accounting for 72.5% of our revenue; and our sales to our largest customer was RMB7.5 million, accounting for 30.4% of our revenue. The revenue generated from the largest customer in 2025 was sales-based royalties, representing the final settlement in 2025 arising from the azvudine we delivered to Fosun Pharmaceutical Industrial prior to the Amendment and subsequently sold by Fosun Pharmaceutical Industrial. We do not expect further revenue to be recognized from the Fosun Pharma Agreements in the future. The tables below summarize the sales to our five largest customers for the period indicated:

Five Largest Customers in 2025	Lengths of Business Relationship	Revenue <i>RMB'000</i>	Percentage of Total Revenue %	Products Provided
Fosun Pharmaceutical Industrial ⁽¹⁾	2022 to present	7,528	30.4	Supply of azvudine
Customer B ⁽²⁾	2025 to present	6,955	28.0	Sales of azvudine
Customer C ⁽³⁾	2024 to present	1,631	6.6	Sales of azvudine
Customer D ⁽⁴⁾	2025 to present	1,074	4.3	Sales of azvudine
Customer E ⁽⁵⁾	2024 to present	791	3.2	Sales of azvudine

Notes:

- (1) Fosun Pharmaceutical Industrial is a company based in Shanghai, primarily engaging in the sales of pharmaceutical products, provision of CMO and CSO services. Its parent company is listed on the Hong Kong Stock Exchange and the Shanghai Stock Exchange.
- (2) Customer B is a government authority in Henan province.
- (3) Customer C is a private company based in Shandong province, primarily engaging in the sales of pharmaceutical products. Its parent company is listed on the Hong Kong Stock Exchange.

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- (4) Customer D is a private company based in Guangdong province, primarily engaging in the sales of pharmaceutical products.
- (5) Customer E is a company based in Yunnan province, primarily engaging in the sales of pharmaceutical products. Its parent company is listed on the Shenzhen Stock Exchange.

None of our Directors or their associates, and none of our existing Shareholders who (to the knowledge of our Directors) own more than five percent of our issued share capital, have any interest in any of our customers during the Track Record Period. None of our major customers during the Track Record Period is also a supplier or vice versa.

QUALITY MANAGEMENT

We have adopted a series of quality assurance procedures to manage our sourcing from suppliers and in-house operations. We have standard operating procedures in respect of the transfer of materials and the training of personnel, among other things. We review relevant documentation provided by our suppliers, inspect the quality of raw materials and conduct regular audits to monitor each manufacturing process to ensure they satisfy our quality standards and requirements. We have also strictly followed and implemented the GMP standards since we commenced the commercialization of azvudine.

INVENTORY MANAGEMENT

After we began in-house manufacturing activities in 2022, our inventories mainly consist of raw materials and finished goods. The shelf-life of azvudine was 12 months, and extended to 24 months in June 2024 (1mg) and August 2024 (3mg). The shelf-life of our APIs range from two to three years. We have built one warehouse in Pingdingshan to store our materials and products under common storage conditions. We have established an inventory management system for our in-house manufacturing activities, including the implementation of temperature and humidity monitoring, CCTV monitoring and a fire alarm system, to achieve effective inventory management. We also use the ERP system to manage the delivery, receipt and storage of our drug products and have developed a monthly inventory check system to conduct regular reviews of our inventories.

The significant inventory write-downs during the Track Record Period were related to finished goods and raw materials impacted by the change of market condition for COVID-19 treatments. As a major public health emergency, the COVID-19 pandemic, influenced by factors such as its evolution, national policy adjustments, and market demand fluctuations, significantly impacted the COVID-19 drug market. Following the full reopening in the fourth quarter of 2022, the COVID-19 pandemic recurred, leading to procurement needs at hospitals at all levels. To address this, we actively stockpiled inventory. However, in May 2023, the World Health Organization declared COVID-19 no longer a “Public Health Emergency of International Concern.” This external policy shift caused substantial changes in market demand, resulting in our significant inventory write-downs. At the end of 2023, we estimated the net realizable value of our inventory based on market expectations and made appropriate accounting adjustments. Subsequently, in 2024, we continued to update our estimates of the net realizable value of inventory based on market changes related to COVID-19 and further accrued inventory write-downs for COVID-19 raw materials based on test results.

We have adopted measures to further improve inventory management, including to (i) improve demand forecasting by combining market trends, historical sales data, and order status for scientific prediction, and (ii) strengthen data analysis to determine reasonable inventory levels, conduct regular inventory aging analysis, establish key indicators, and promptly handle abnormal data.

INTELLECTUAL PROPERTY

Intellectual property rights are important to our success. Our future commercial success depends in part on our ability to obtain and maintain patent and other intellectual property and proprietary protections for our compounds, technologies, inventions and improvements related to our drug candidates, as well as on our ability to defend and enforce our intellectual property rights including any patent that we have or may obtain in the future. As of the Latest Practicable Date, we held 24 patents in China and 39 patent applications pending in China. As of the same date, we also had 27 patents and 31 patent applications pending overseas. We are the sole owner of all patents relating to our Core Products. In addition, as of the Latest Practicable Date, we held 45 trademarks in Chinese Mainland and Hong Kong. During the Track Record Period and up to the Latest Practicable Date, we were not involved in any material proceedings in respect of, and we had not received notice of any material claims of infringement of, any intellectual property rights that are threatened or pending, in which we may be a claimant or a respondent. For further details, please refer to Appendix IV to this document.

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We have exclusive ownership of all the IP rights relating to our Core Products. The table below lists the material patents and patent applications as of the Latest Practicable Date:

Patent Name	Corresponding Product/ Indication	Patent Type	Registration/ Application No.	Owner/ Applicant	Source of Patent	Status	Application Date	Expiry Date	Jurisdiction
CRYSTAL FORM A OF 2'-FLUORO-4'-SUBSTITUTED NUCLEOSIDE ANALOG I AND PREPARATION METHOD THEREFOR AND USE THEREOF (2'-氟-4'-取代核苷類似物的晶型A及其製備方法和應用)	Azvudine	Invention Patent	201910313694.7	Henan Genuine	Developed through Independent R&D	Granted	2019.04.18	2039.04.18	PRC
2'-FLUORINE-4'-SUBSTITUTED NUCLEOSIDE ANALOGUES, PREPARATION METHODS AND USES THEREOF (2'-氟-4'-取代核苷類似物、其製備方法及應用)	Azvudine	Invention Patent	200710137548.0	Henan Genuine	Acquired from Third Parties ¹	Granted	2007.08.07	2027.08.07	PRC
2'-FLUORINE-4'-SUBSTITUTED-NUCLEOSIDE ANALOGUES, PREPARATION METHODS AND USES THEREOF	Azvudine	Invention Patent	US12669342	Henan Genuine	Acquired from Third Parties ¹	Granted	2008.06.27	2028.12.07	U.S.
2'-FLUORO-4'-SUBSTITUTED-NUCLEOSIDES, THE PREPARATION AND USE	Azvudine	Invention Patent	EP08772992.7	Henan Genuine	Acquired from Third Parties ¹	Granted	2008.06.27	2028.06.27	Germany, France, UK
CRYSTAL FORM A OF 2'-FLUORO-4'-SUBSTITUTED NUCLEOSIDE ANALOG I AND PREPARATION METHOD THEREFOR AND USE THEREOF	Azvudine	Invention Patent	AU2019435643	Henan Genuine	Developed through Independent R&D	Granted	2019.04.18	2039.04.18	Australia
2'-fluorine-4'-Azide-Pharmaceutical applications of nucleoside analogs or their salts (2'-氟-4'-疊氮-核苷類似物或其鹽的藥物應用)	Azvudine anti-tumor	Invention Patent	201010506595.X	Henan Genuine	Acquired from Third Parties ¹	Granted	2010.10.08	2030.10.08	PRC
Use of nucleoside compounds in treating coronavirus infectious diseases (核苷類化合物在治療冠狀病毒感染性疾病中的用途)	Azvudine for the treatment of COVID-19	Invention Patent	202010125799.2	Henan Genuine	Developed through Independent R&D	Granted	2020.02.27	2040.02.27	PRC

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Patent Name	Corresponding Product/ Indication	Patent Type	Registration/ Application No.	Owner/ Applicant	Source of Patent	Status	Application Date	Expiry Date	Jurisdiction
Antitumor pharmaceutical composition comprising azvudine and a chemotherapeutic agent (包含阿茲夫定和化療試劑的抗腫瘤藥物組合物)	Azvudine anti-tumor	Invention Patent	202310201602.2	Henan Genuine	Developed through Independent R&D	In application	2023.03.03	N/A	PRC
Antitumor pharmaceutical composition containing azvudine (包含阿茲夫定的抗腫瘤藥物組合物)	Azvudine anti-tumor	Invention Patent	202310201580.X	Henan Genuine	Developed through Independent R&D	In application	2023.03.03	N/A	PRC
Immunomodulatory compositions comprising azvudine (包含阿茲夫定的免疫調節劑組合物)	Azvudine anti-tumor	Invention Patent	202310232465.9	Henan Genuine	Developed through Independent R&D	In application	2023.03.10	N/A	PRC
A pharmaceutical composition, its formulation and its use (一種藥物組合物、其製劑及其用途)	Azvudine anti-tumor	Invention Patent	202610378951.5	Henan Genuine	Developed through Independent R&D	In application	2025.03.28	N/A	PRC
Anticancer drugs containing azvudine and uses thereof (包含阿茲夫定的抗腫瘤藥物及其用途)	Azvudine anti-tumor	Invention Patent	202510735722.X	Henan Genuine	Developed through Independent R&D	In application	2025.03.28	N/A	PRC
Azvudine or its pharmaceutically acceptable salts, or new pharmaceutical uses of them in combination with HIV inhibitors (阿茲夫定或其藥學上可接受的鹽或它們與HIV抑制劑聯用的新的藥物用途)	Azvudine for the treatment of INRs in HIV - infected patients	Invention Patent	202610533453.3	Henan Genuine	Developed through Independent R&D	In application	2025.06.03	N/A	PRC
Pharmaceutical composition and use of menin inhibitor combined with azvudine (Menin抑制劑與阿茲夫定聯用的藥物組合物及用途)	Azvudine anti-tumor	Invention Patent	202510930770.4	Henan Genuine	Developed through Independent R&D	In application	2025.07.07	N/A	PRC
Pharmaceutical compositions containing azvudine and uses thereof (包含阿茲夫定的藥物組合物及其用途)	Azvudine anti-tumor	Invention Patent	202510873838.X	Henan Genuine	Developed through Independent R&D	In application	2025.06.26	N/A	PRC
ANTI-TUMOR PHARMACEUTICAL COMPOSITION COMPRISING AZVUDINE	Azvudine anti-tumor	Invention Patent	US18199402	Henan Genuine	Developed through Independent R&D	Granted	2023.05.19	2043.05.19	USA

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Patent Name	Corresponding Product/ Indication	Patent Type	Registration/ Application No.	Owner/ Applicant	Source of Patent	Status	Application Date	Expiry Date	Jurisdiction
Crystal form a of 2'-fluoro-4'-substituted nucleoside analog i and preparation method thereof and use thereof	Azvdine	Invention Patent	EP19920547.7	Henan Genuine	Developed through Independent R&D	Granted	2019.04.18	2039.04.18	Europe
Anti-tumor pharmaceutical compositions comprising azvdine and an EGFR/TKI inhibitor	Azvdine anti-tumor	Invention Patent	US18199402	Henan Genuine	Developed through Independent R&D	Granted	2023.5.19	2043.05.19	USA
Antitumor pharmaceutical composition comprising azvdine and chemotherapeutic agent	Azvdine anti-tumor	Invention Patent	US18200000	Henan Genuine	Developed through Independent R&D	Granted	2023.05.22	2043.05.22	USA
Anti-tumor pharmaceutical compositions comprising azvdine and an EGFR/TKI inhibitor	Azvdine anti-tumor	Invention Patent	EP23174301.4	Henan Genuine	Developed through Independent R&D	Granted	2023.05.19	2043.05.19	Europe
Antitumor pharmaceutical composition comprising azvdine and chemotherapeutic agent	Azvdine anti-tumor	Invention Patent	EP23174495.4	Henan Genuine	Developed through Independent R&D	Granted	2023.05.22	2043.05.22	Europe
Immunomodulator composition comprising azvdine	Azvdine anti-tumor	Invention Patent	US18205628	Henan Genuine	Developed through Independent R&D	In application	2023.06.05	N/A	USA
Immunomodulator composition comprising azvdine	Azvdine anti-tumor	Invention Patent	EP23177216.1	Henan Genuine	Developed through Independent R&D	In application	2023.06.05	N/A	Europe
CRYSTAL FORM, PREPARATION METHOD, AND APPLICATION OF 4'-SUBSTITUTED NUCLEOSIDE (4'-取代核苷的晶型、製備和應用)	CL-197	Invention Patent	201910216375.4	Henan Genuine	Acquired from Third Parties ²	Granted	2019.03.21	2039.03.21	PRC
Crystal form, preparation method, and application of 4'-substituted nucleoside	CL-197	Invention Patent	US17604451	Henan Genuine	Acquired from Third Parties ²	Granted	2019.03.21	2039.03.21	USA

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Patent Name	Corresponding Product/ Indication	Patent Type	Registration/ Application No.	Owner/ Applicant	Source of Patent	Status	Application Date	Expiry Date	Jurisdiction
2-(2,4,5-SUBSTITUTED PHENYLAMINO) PYRIMIDINE DERIVATIVE AND PREPARATION METHOD THEREFOR AND USE OF ANTI-TUMOR DRUGS THEREOF (2-(2,4,5-取代苯氨基)嘧啶衍生物，其製備方法及其在製備抗腫瘤藥物中的應用)	Dosimertinib	Invention Patent	201711282598.8	Henan Genuine	Acquired from Third Parties ³	Granted	2017.12.07	2037.12.07	PRC
PREPARATION METHOD AND INTERMEDIATE OF DEUTERATED ACRYLAMIDE (氘代丙烯酸酯的製備方法和中間體)	Dosimertinib	Invention Patent	201710949642.X	Henan Genuine	Acquired from Third Parties ³	Granted	2017.10.12	2037.10.12	PRC
2-(2,4,5-SUBSTITUTED PHENYLAMINO) PYRIMIDINE DERIVATIVE AND CRYSTALLINE FORM B THEREOF Benzoic acid compounds and their preparation methods and applications (苯甲酸類化合物及其製備方法和應用)	Dosimertinib crystalline form MTB-1806	Invention Patent	US17497994 201910191840.3	Henan Genuine Henan Genuine	Acquired from Third Parties ³ Acquired from Third Parties ⁴	Granted	2021.10.11 2019.03.14	2041.10.11 2039.03.14	USA PRC
Benzoic acid compound and method for preparing the same	MTB-1806	Invention Patent	US17026339	Henan Genuine	Acquired from Third Parties ⁴	Granted	2020.09.21	2040.09.21	USA
BENZOIC ACID COMPOUNDS AND PREPARATION METHOD THEREFORE AND APPLICATIONS THEREOF	MTB-1806	Invention Patent	EP19772121.0	Henan Genuine	Acquired from Third Parties ⁴	Granted	2019.03.14	2039.03.14	Europe
A broad-spectrum viral membrane fusion inhibitor and its preparation method and use (一種廣譜病毒膜融合抑制劑及其製備方法和用途)	Broad-spectrum antiviral peptides	Invention Patent	202310276398.0	Henan Genuine	Acquired from Third Parties ⁵	In application	2023.03.20	N/A	PRC

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Notes:

- (1) Chang Junbiao's team designed the core chemical structure of azvudine, developed its synthesis methods and conducted preliminary in vitro activity evaluation, providing the basis for subsequent development. Chang Junbiao, one of the primary inventors of the relevant patents, was not involved in any subsequent R&D work of the underlying drug candidates following the transfer of such patents to our Group. Accordingly, we do not consider that Chang Junbiao's contribution to the relevant drug candidate during the initial stage of its R&D has materially affected the independence or sufficiency of our internal R&D capabilities.
- (2) Meitaibao's team designed the core chemical structure of CL-197, developed its synthesis methods and conducted preliminary in vitro anti-HIV bioactivity evaluation, providing the basis for subsequent development. Meitaibao is a biotech company primarily focused on drug R&D founded by Dr. Du.
- (3) Meitaibao's team designed the core chemical structure of dosimertinib, developed its synthesis methods and conducted preliminary in vitro anti-HIV bioactivity evaluation, providing the basis for subsequent development. Meitaibao is a biotech company primarily focused on drug R&D founded by Dr. Du.
- (4) Meitaibao's team designed the core chemical structure of MTB-1806, developed its synthesis methods and conducted preliminary in vitro anti-HIV bioactivity evaluation, providing the basis for subsequent development. Meitaibao is a biotech company primarily focused on drug R&D founded by Dr. Du.
- (5) Professor He Yuxian's team designed the core polypeptide structure, developed the preparation process, and conducted in vitro studies, providing the basis for subsequent development.

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We consider that the acquired IPs are the necessary technological starting point for the development of our relevant drug candidates. Following the acquisitions, we have invested significant resources in in-depth development and value creation of our drug candidates. We have adopted a patent strategy that extends the life cycle of our products through multi-dimensional strategic planning and technological innovation so as to address the risk of patent expiration and build up technological barriers. We have established a “basic patents – peripheral patents – territorial barriers” three-layered intellectual property protection system. For instance, with respect to azvudine, such patent protection strategy is implemented as follows:

Level of protection	Type of patent	Illustrative examples of patents/patent applications	Term of protection	Function of patent protection
Basic protection	Basic patent for the chemical compound	ZL200710137548.0 (core structure)	Expires in 2027	Original drug to dominate the market (2007 to 2027)
Expanded protection	Patents for crystal form/formulation patents	ZL201910313694.7 (crystal form)	Expires in 2039	Establish patent barriers against generic drugs (bioequivalence barriers)
	Patents for indications/monotherapies	ZL201010506595.X (monotherapy against cancers)	Expires in 2030	Expand into new market (oncology)
	Patents and patent applications for indications/combination therapies	202310232465.9 (immune activation and combination therapy with anti-PD-1)	In application. Term of protection will expire in 2043 if patent is granted	Expand into new market (oncology/immunomodulation)

Our patent strategy extends the technological life cycle of azvudine through improved patents (such as crystal form/formulation patents) and expanded indications (such as oncology/immunomodulation), and constructs peripheral technological barriers through international patent strategies (such as PCT applications and Supplementary Protection Certificate in EU). We have submitted a number of patent applications and been granted with a number of patents relating to azvudine and azvudine for specific indications with the original expiration dates ranging from 2027 to after 2040. In addition, according to the PRC Patent Law, to compensate for the time consumed by the review and approval process for the marketing of a new drug, the patent administrative authority in China shall grant a patent term extension of no more than five years with respect to invention patents of a new drug that has obtained the marketing approval in China. See “Regulatory Overview—Laws and Regulations Relating to Intellectual Property—Patents.” We may rely on such extension, if successfully granted. With such established intellectual property protection system and the legal regime, the two patents that will be originally expiring in 2027 and 2030 will not have material adverse impact on our business operations. We have adopted the same patent strategy for our other drug candidates.

A freedom-to-operate search and analysis (“**Core Product FTO Analysis**”) has been conducted in China in relation to our Core Products, including (i) azvudine, our Core Product, for the treatment of viral infections and oncological diseases including blood cancers and solid tumors, as well as azvudine + anti-PD-1 for the treatment of liver cancer and colorectal cancer, azvudine + dosimertinib for the treatment of NSCLC, azvudine/CL-197 for the treatment of HIV and azvudine + CTX for the treatment of lymphoma; (ii) CL-197, our Core Product, for the treatment of HIV infection; and (iii) dosimertinib, our Core Product, for the treatment of NSCLC. In addition, we have voluntarily conducted a freedom-to-operate search and analysis (“**Other Drug FTO Analysis**”) and, together with the Core Product Core Product FTO Analysis, “**FTO Analysis**”) in China in relation to (i) ZSSW-136 for the treatment of malignant tumor, and (ii) MTB-1806 for the treatment of AIS. Based on the FTO Analysis and as advised by our PRC IP Advisors, we have implemented relatively comprehensive patent protection for our five drug candidates, and the risk of IP infringement arising from our development and commercialization of the five drug candidates in China is low.

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COMPETITION

The development and commercialization of innovative drugs is highly competitive. While we believe our innovative platform provides us with competitive advantages, we face competition from global and China-based pharmaceutical and biotech companies that market or will market products in competition with our drug and drug candidates. We primarily rely on our R&D capabilities, the clinical performance of our drug and drug candidates, our commercialization capabilities and brand recognition in the market competition.

For further details of our major competitors, see “—Our Product Portfolio” and “Industry Overview” in this document.

EMPLOYEES

We had 212 employees as of December 31, 2025, with the vast majority of which based in China. The table below sets forth our employees by function and by geographical region as of the same date:

Function	Number of Employees in PRC	Number of Employees in Hong Kong
R&D	77	—
Administration	11	1
Commercialization and supply chain	76	—
Operation management	41	—
Senior management	6	—
	211	1
Total		212

To comply with PRC labor laws, we enter into standard employment agreements with all employees in China, which include strict confidentiality obligations and require return of company materials upon termination. The confidentiality obligation of an employee remains effective for two years after the employment agreement is terminated. We have also entered into additional non-compete agreements with our key employees that they may not conduct business in direct or indirect competition with us during employment and for two years after the termination. As required by PRC labor laws, we make contributions to social insurance and housing provident funds for our employees based in China. During the Track Record Period, we engaged third-party agents to make such contributions locally on behalf of us for some of our employees located outside Beijing, Shenzhen, Shanghai, Pingdingshan and Zhengzhou for the following reasons: (i) we recruited certain experienced talents from other cities for the construction of the Pingdingshan production base, who elected to contribute social security and housing provident fund contributions in their place of household registration; and (ii) as our marketing team members are scattered across different cities nationwide, with some cities having only one employee, we do not have local subsidiaries to act as the contributing employer in each of the cities. We therefore engage third-party agents to make contributions locally on behalf of us. See “Risk Factors—Risks Relating to Our Industry and Business Operations—Any failure to comply housing provident fund or the mandatory social insurance may subject us to fines and other legal or administrative sanctions” in this document for details. The amounts paid through third-party agents were RMB1.1 million in 2024 and RMB1.4 million in 2025. We have not received any inquiries, questions, investigations, administrative penalties, or any other regulatory measures from the relevant social security and housing provident fund authorities regarding the third-party agents arrangements. Henan Genuine has registered a branch in Zhengzhou and opened social security and housing provident fund accounts locally to reduce the number of employees using third-party agents for social security and housing provident fund payments. As of December 31, 2025, the number of employees using third-party agents for these payments was 13. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any labor disputes or strikes that would materially and adversely affect our business, financial condition or results of operations.

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We recruit our employees mainly through recruiters on online recruiting platforms. We offer remuneration packages based on individuals' qualifications and experiences and generally match the market rate for salary to stay competitive in the labor market. We also provide training and development programs to our employees from time to time to ensure their awareness and compliance with our various policies and procedures and to maintain certain requisite qualifications, such as quality assurance and good pharmacovigilance practice qualifications. In addition, we award various incentives to encourage inventions by our R&D team. We believe that we maintain a good working relationship with our employees and we did not experience any difficulty in recruiting staff for our operations during the Track Record Period.

INSURANCE

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. In line with industry practice in China, we maintain different types of insurance policies, such as personal accident insurance and clinical trials liability insurance. Our Directors consider that our existing insurance coverage is generally in line with the industry practice in China. See "Risk Factors—Risks Relating to Our Industry and Business Operations—We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources" in this document for details.

PROPERTIES AND FACILITIES

Our headquarters and manufacturing facilities are located in Pingdingshan, Henan Province. As of the Latest Practicable Date, we did not own any real property. As of the same date, we leased five properties with an aggregate GFA of approximately 26,000 sq.m. in China for daily business operations, R&D and in-house manufacturing, one of which were leased from Pingdingshan Xingyu. As the lessee of the leased properties, we are not required under the PRC laws and regulations to obtain the construction work planning permit, the construction work commencement permit or the housing ownership certificate, or to complete the relevant fire safety procedures, provided that we do not carry out any additional construction works on such leased properties. Accordingly, no such permits or procedures are required in respect of our production lines.

As of the Latest Practicable Date, two lease agreements relating to our leased properties in China had not been filed with the relevant PRC housing administration authorities. According to the relevant PRC laws, a company may be subject to an administrative fine up to a maximum of RMB10,000 for each lease agreement that is not filed with the relevant PRC housing administration authority, if the company fails to rectify such non-compliance under the prescribed time limit, which we do not believe will have a material adverse impact on our business.

During the Track Record Period and up to the Latest Practicable Date, we also experienced certain incidents in relation to our business operations on the properties in Pingdingshan that we leased from Pingdingshan Xingyu. Prior to commencing operations, Pingdingshan Xingyu failed to complete certain construction procedures, including (i) obtaining the construction work planning permit and the construction work commencement permit, and consequentially obtaining the housing ownership certificate, (ii) completing the required fire prevention procedures and (iii) obtaining the approval documents for its environmental impact assessment (EIA) report and conducting the inspection upon construction of its environmental protection projects as required by law and regulations in the PRC. Pingdingshan Xingyu and we have been proactive in rectifying such non-compliance and seeking confirmations from the competent authorities to continue our operations. As of the Latest Practicable Date, we had obtained the approval documents and conducted inspections under (iii) above. In addition, we have also obtained the written confirmations from each of the competent authorities that no administrative penalties or measures will be imposed on us or Pingdingshan Xingyu and neither we nor Pingdingshan Xingyu will be held liable for those previous non-compliance. In addition, each of the competent authorities confirmed that we may continue our operations therein and that they will not order Pingdingshan Xingyu or us to suspend, restore or relocate from such leased properties. As a result, as advised by our PRC Legal Advisors, the risks that we will be imposed of administrative penalties or measures by the competent authorities due to such non-compliance is low.

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Additionally, as of the Latest Practicable Date, we had one leased property in Shenzhen where the actual use did not conform to the intended use as recorded in the property ownership certificate. As advised by our PRC Legal Advisors, the competent authorities may order us to rectify such non-compliance within a prescribed time period, prohibit us from using the property, and/or terminate our lease agreement for these properties. See “Risk Factors—Risks Relating to Our Industry and Business Operation—We do not own any real property and may incur substantial relocation expenses if any lease for our offices is not renewed upon its expiration or is terminated” in this document for risks related to our leased properties.

Leasing Arrangements with Pingdingshan Xingyu

On December 27, 2018, Henan Genuine entered into a leasing agreement (as renewed on January 20, 2022, July 1, 2022 and August 9, 2022, the “PX Leasing Agreement”) with Pingdingshan Xingyu to rent certain facilities with an aggregate GFA of approximately 22,262.3 sq.m. in Pingdingshan at a monthly rent of RMB333,935.1, on terms that are comparable to market terms and other independent transactions. The term of the PX Leasing Agreement lasts from January 1, 2019 to December 31, 2038, and the monthly rent is RMB333,935.1. We consider such transaction was fair and reasonable taking into consideration the market rent of comparable real properties.

Pingdingshan Xingyu was initially established to develop a specialty membrane business. However, due to the business did not meet the shareholders’ expectations, and in order to revitalize its idle property assets, Pingdingshan Xingyu explored other business opportunities in the second half of 2018 and finally signed a lease agreement with us on December 27, 2018. This move confirmed the commercial viability of the new business before formally changing its business scope.

In 2019, Pingdingshan Xingyu conducted further constructions on the leased properties and incurred construction costs while experiencing cash flow problems. As a result, in June 2019, the parties agreed that Henan Genuine would pay the construction costs on behalf of Pingdingshan Xingyu, with its own working capital, to offset the rent due from Henan Genuine to Pingdingshan Xingyu. On March 23, 2022, Henan Genuine and Pingdingshan Xingyu entered into an agreement (the “Offset Agreement”) to memorialize such arrangement. Pursuant to the Offset Agreement, because the amount of construction costs paid by Henan Genuine on behalf of Pingdingshan Xingyu as of December 31, 2021, being RMB24.6 million, exceeded the rent due to Pingdingshan Xingyu as of the same date, being RMB11.0 million, the construction costs paid by Henan Genuine was first used to offset the rent due to Pingdingshan Xingyu as of December 31, 2021, with the remaining amount agreed to be applied to the rent that will become due under the PX Leasing Agreement. By April 2025, the total amount of construction costs paid by Henan Genuine had fully offset the rent due to Pingdingshan Xingyu.

SOCIAL, HEALTH, SAFETY AND ENVIRONMENTAL MATTERS

We are subject to various social, health, safety and environmental laws and regulations and our operations are regularly inspected by local government authorities. See “Regulatory Overview—Laws and Regulations Relating to Environmental Protection and Fire Prevention” in this document for details. We believe we have adequate policies ensuring compliance with all applicable social, health, safety and environmental protection regulations. We intend to create a lasting positive environmental, social and governance (“ESG”) impact on our customers, suppliers and the broader community whom our operation may impact. We acknowledge our responsibilities on environmental protection, social responsibilities and are aware of the climate-related issues that may have impact on our business. We are committed to complying with ESG reporting requirements upon [REDACTED].

ESG strategies and risk management

We have a deep understanding of the key role of ESG in its business development, financial performance and operation. By comprehensively considering major concerns of internal and external stakeholders, and by integrating our business characteristics, we accurately identified and conducted in-depth analysis of ESG risks that may have material impacts on the Company, and taking into account of these risks in our strategic planning, financial initiatives and operation.

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We have identified and assessed the following major ESG risks that may have impacts on our business, strategic or financial performance, and have formulated relevant counter measures:

- **Climate change:** Climate change and increasing extreme weather events could have impacts on the steadiness of our operations, while regulations such as carbon taxes, fuel or energy taxes and pollution limits could result in higher direct costs. We have started monitoring of greenhouse gas emission. We committed to continuously reduce greenhouse gas emission, thereby facilitating the transformation of the Company towards one with low carbon and green operational model.
- **Product liabilities:** Any health or safety incident or quality concern related to our drugs could lead to compliance risks. We have strictly followed and implemented the GMP standards since we commenced the commercialization of azvudine. We have quality assurance procedures that covers the whole life cycle of our drugs.
- **Business ethics:** Any business practice in violation of regulations could constitute violation of laws and regulations, expose us to penalties and cause damage to our reputation. We have established comprehensive systems to regulate activities of related parties including employees and suppliers. We have zero-tolerance for any act of corruption, with a good business environment and order for development maintained by our employees at all levels.

We continued to optimize procedures of risk management and internal control, effectively identified, assessed, prioritize and monitor major ESG-related risks through systematic procedures, and gradually integrated these risks into our overall risk management and internal control framework. The Board as the highest decision-making body are responsible for conducting careful studies and discussion on materiality and priorities of major ESG risks and making final decisions.

In respect of the identified ESG risks, we have developed targeted counter-measures to ensure implementation of risk control measures across different stages of operating procedures. We will adopt appropriate measures to hedge these risks when necessary, thereby comprehensively enhancing our capacity to manage risks. During the Track Record Period and up to the Latest Practicable Date, we did not have any non-compliance in violation of ESG-related laws and regulations.

Social Matters

In respect of social responsibilities, we are committed to offering a fair and caring working environment to our employees. We have transparent policies on recruitment, compensation, dismissal, equal opportunities, diversity and anti-discrimination. We hire employees based on their merits and it is our corporate vision to offer equal opportunities to our employees. We encourage our employees who encounter any discrimination to seek immediate assistance, which also allows us to conduct timely investigation and follow up as needed. In addition, we provide training programs on industry and regulatory developments to our employees.

Furthermore, we actively engage in fulfilling our social responsibilities; as of the Latest Practicable Date, we and Fosun Pharma jointly donated nearly 300,000 bottles of Azvudine tablets to special high-risk groups in China, including rural areas and urban nursing homes, and welfare institutions. Our donation covered more than 250 cities and counties and helped certain regions and demographics to address the lack of medication supplies and medical facilities.

Occupational Health and Safety

Our operations involve the use of hazardous and flammable chemical materials. We have strictly followed the environmental, health and safety (EHS) standards and guidelines for operating in our laboratory. Our EHS manager is mainly responsible for identifying and mitigating safety risks, improving the safety production policies and procedures, supervising the implementation of such policies and procedures and making emergency plans in respect of production safety to our employees. We have adopted and maintained a series of rules, standard operating procedures and measures to maintain a healthy and safe environment for our employees. We have relevant internal policies in place to ensure safe storage and handling of flammable and corrosive materials used in our laboratory. We also have safety equipment and instruments in place.

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Data Privacy Protection

We have established procedures to protect the confidentiality of patients' data. We implement strict internal policies to govern the collection, handling, storage, retrieval of, and access to our patients' personal data and medical records and protect the security and confidentiality of personal information to ensure compliance with all applicable national or international rules and regulations on data protection and privacy. Our information technology network is configured with multiple layers of protection to secure our databases and servers. We have also implemented a variety of protocols and procedures to safeguard our data assets and prevent unauthorized access to our network. In order to strengthen the management of our database, we have designated database administrator to carry out the responsibilities of daily maintenance, authority control, security protection and other management of the database. Additionally, we require external parties and internal employees involved in clinical trials to comply with confidentiality requirements. Data are to be used only for the intended use, as agreed by the patients and consistent with the informed consent form. Furthermore, we enter into confidentiality agreements with our employees who have access to any aforementioned privacy information, make sure employees are legally obligated not to misuse the confidential information while in office, to surrender all confidential information in possession while resigning, and to retain their confidential obligations after they leave office. We also implement a series of measures to ensure our employees' compliance with our data security measures. For instance, we provide training to our employees on relevant data security policies.

According to our PRC Legal Advisors, as of the Latest Practicable Date, we had not transferred any clinical data outside the PRC and had complied, in all material respects, with applicable PRC laws and regulations on cross-border data transfers. During the Track Record Period and up to the Latest Practicable Date, we did not experience any breach of confidential client information or any other client information-related incidents which could cause a material adverse effect on our business, financial condition or results of operations. During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any material penalty in relation to data privacy.

Patient Safety

During the clinical study period, if the subjects experience any discomfort, investigators will provide necessary treatment to the subjects and closely follow up on their health conditions. If the subjects experience serious adverse events during the clinical study, investigators will examine them and provide appropriate treatment. In the event of any damage related to the clinical study during the research period, the subjects will be compensated in accordance with the relevant laws and regulations and insurance policies sponsor purchased for such clinical trial liabilities. At the same time, according to the clinical study plan, the subjects shall return to the research center regularly for visits, during which relevant safety tests will also be arranged.

Environmental Matters

We are acutely aware of the impact of our business on climate and environment. We strive to take measures to protect the ecological environment during our business operation, so as to minimize adverse environmental impact.

After we began in-house manufacturing activities in 2022, the main pollutants produced from our manufacturing facilities include wastewater, waste gas, solid waste and noise. Wastewater includes production process wastewater, equipment cleaning wastewater, laboratory wastewater and domestic wastewater. Production wastewater is mainly discharged into the municipal water pipe network after treatment while domestic wastewater is discharged into the municipal sewage pipe network through the septic tank in our manufacturing facilities. Our wastewater treatment methods are in compliance with the national treatment and discharge standards. For any potential hazardous waste we produce from R&D activities, we engage third parties for the disposal of such hazardous materials and wastes. We select these third parties based on a number of factors, including their qualification, service quality and industry experience.

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We pay close attention to the global trend and China's national strategy of addressing climate change and ecological environment protection. In terms of major climate change-related initiatives or action plans that may affect us, we plan to formulate policies after our [REDACTED] to systematically identify, assess and manage climate change-related risks, and formulate relevant response strategies.

We destroy our products in accordance with the requirements of our internal policy, namely "Non-conforming Product Management" (QAM-31). We may also entrust third-party companies with destruction qualifications to destroy non-conforming products containing raw materials or hazardous chemicals, so as to reduce the impact on the environment.

Resource Consumption

In pursuit of our sustainable development objectives, we rigorously oversee our environmental protection performance across various domains, including resource efficiency and energy consumption. We closely monitor our electricity, gas and water consumption levels and actively implement strategies to enhance energy efficiency and promote water conservation. In aggregate, in terms of our manufacturing function which has been the primary resource consumption function in our Group, our electricity consumption levels were approximately 1.7 million kWh and 2.4 million kWh, respectively, in 2024 and 2025; our gas consumption levels were approximately 2,500 m³ and 2,500 m³, respectively, in 2024 and 2025; and our water consumption levels were approximately 59,000 m³ and 45,000 m³, respectively, in 2024 and 2025.

Aligned with the ESG evaluation system standards in China and industry best practices, we are committed to mitigating or minimizing the adverse environmental impacts resulting from our operations. We develop environmental management plans aimed at continually enhancing our energy consumption efficiency and ensuring compliance with all governmental environmental regulations and requirements. Our current objective is to establish a robust ESG governance mechanism and system for our Company. The historical energy consumption data from the Track Record Period will serve as a foundational basis for devising pertinent energy reduction strategies and establishing suitable reduction targets for the future. This goal reflects our endeavor to strike a balance between advancing our R&D and manufacturing endeavors over the next three years, while also upholding our environmental commitment. We plan to achieve this by optimizing processes to maximize electricity and gas utilization and minimize water wastage in our daily operations.

To achieve our goals, we have already implemented the following environmentally friendly measures: (1) promote environmental awareness among all staff by encouraging them to minimize paper waste and conserve water, gas and electricity resources, such as placing water-saving and power-saving signs in prominent areas to capture attention and foster our employees' commitment to environmental protection; (2) encouraging our employees to avoid printing hard copies and requiring double-sided printing whenever possible; (3) regularly conducting inspections of our laboratory equipment in order to check for abnormal conditions, and make prompt report to avoid potential damages; (4) carrying out manual check after shift to eliminate unnecessary lighting; and (5) promoting recycling schemes, seeking alternative ways of disposing of and reducing waste in environmental-friendly ways.

During the Track Record Period and up to the Latest Practicable Date, we had been in compliance with the relevant PRC laws and regulations in all material aspects, and had not been subject to any material claim or penalty in relation to health, safety, social and environmental protection, or been involved in any significant work place accident or fatality. We intend to remain in strict compliance of all applicable PRC laws and regulations.

LICENSES AND PERMITS

We are required to obtain and renew certain licenses, permits, approvals and certificates for our business operations in China. Our PRC Legal Advisors are of the view that, during the Track Record Period and up to the Latest Practicable Date, we had obtained all requisite licenses, permits, approvals and certificates from the relevant government authorities that are material for our

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business operations in China, including registrations and drug manufacturing. The following table sets out a list of material licenses and permits held by us as of the Latest Practicable Date. We plan to renew all material licenses and permits upon expiration.

Holder	License/Permit	Indication	License/ Permit No.	Validity Period	Authority
Henan Genuine	Manufacturing License for Pharmaceutical Products	N/A	豫20210344	August 14, 2025 – May 21, 2031	Henan Medical Products Administration
Henan Genuine	Drug Registration Certificate (Azvudine Tablets (1 mg))	HIV infection	2021S00825	July 20, 2021 – July 19, 2026	NMPA
Henan Genuine	Drug Registration Certificate (Azvudine Tablets (3 mg))	HIV infection	2021S00826	July 20, 2021 – July 19, 2026	NMPA
Henan Genuine	Drug Registration Certificate (Azvudine Tablets (1 mg))	Common COVID-19	2022S00715	July 25, 2022 – July 24, 2026	NMPA

COMPLIANCE AND LEGAL PROCEEDINGS

We may be involved in legal proceedings in the ordinary course of business from time to time. During the Track Record Period and up to the Latest Practicable Date, none of us were involved in any litigation, arbitration or administrative proceedings which could have a material adverse impact on our business, financial condition or results of operations. As of the Latest Practicable Date, we were not aware of any pending or threatened litigation, arbitration or administrative proceedings against us which may have a material and adverse impact on our business, financial condition or results of operations.

During the Track Record Period and as of the Latest Practicable Date, we had not had any non-compliance incidents which our Directors believe would, individually or in the aggregate, have a material operational or financial impact on our company as a whole.

AWARDS AND RECOGNITIONS

We and our management have received various awards and recognitions, including the following:

Awardee	Award	Year of Award	Awarding Organization
Henan Genuine	Most Investment Potential Award (最具投資潛力獎)	2025	Cailianpress (財聯社)
Henan Genuine	Excellent Biopharmaceutical Company of the Year (年度卓越生物醫藥企業)	2025	GuruClub (格隆匯)
Henan Genuine	List of Top 101 Chinese Pharmaceutical Industry and Top 10 Core Industrial Chains in 2025 – Top 101 Chinese Innovative Pharmaceutical Companies in 2025 (2025中國製藥工業Top 101及10大核心產業鏈榜單2025中國創新藥企Top 101)	2025	The 7th CMC-China China Pharmaceutical Industry Expo (第七屆CMC-China中國製藥工業博覽會)

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Awardee	Award	Year of Award	Awarding Organization
Henan Genuine	BIOCHINA Awards 2024 Innovation Breakthrough Enterprise Award (BIOCHINA Awards “2024創新突破企業獎”)	2025	BIOCHINA 2025 10th E-commerce Bio-industry Conference (BIOCHINA 2025 第十屆易貿生物產業大會)
Henan Genuine	First prize of the Henan Province Technological Invention Award (河南省技術發明獎一等獎) (regarding azvudine as a dual-target HIV treatment)	2024	The People’s Government of Henan Province (河南省人民政府)
Henan Genuine	2023 Top 30 Innovative Small-Molecule Pharmaceutical Enterprises in China (2023年度中國小分子藥物企業創新力TOP30)	2024	MENET (米內網)
Henan Genuine	Best Business Return Award for Drugs Entering the Market for Three Years (Chemical Drugs) (上市三年“最佳商業回報獎(化學藥)”)	2024	CBIITA (中國生物醫藥產業鏈創新轉化聯合體)

RISK MANAGEMENT AND INTERNAL CONTROL

We are exposed to various risks in the operations of our business, and we believe that risk management is important to our success. For details, see “Risk Factors—Risks Relating to Our Industry and Business Operations” in this document. We are exposed to a variety of market and other financial risks. See “Financial Information—Market and Other Financial Risks” in this document for details. We have devoted ourselves to establishing and maintaining risk management and internal control systems consisting of policies, procedures and risk management methods that we consider to be appropriate for our business operations, and we are dedicated to continuously improving these systems. Our Directors oversee and manage the overall risks associated with our operations. We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control. To monitor the ongoing implementation of our risk management policies and corporate governance measures after the [REDACTED], we have adopted or will continue to adopt, among other things, the following internal control and risk management policies in our business operations.

Internal Control Risk Management

Our Board [has established] the Audit Committee to review and supervise our financial reporting process and internal control system. For the qualifications and experience of these committee members, see “Directors and Senior Management” in this document. In addition, our internal audit team works closely with our business team to (i) perform risk assessments and give advice on risk management strategies, (ii) improve operation efficiency and monitor internal control effectiveness, and (iii) promote risk awareness. We have adopted or will continue to adopt strict internal procedures to ensure the compliance of our business operations with the relevant rules and regulations.

In accordance with our procedures, our financial and legal personnel will examine the agreement terms and review all relevant documents for our business operations before we enter into any agreement or business arrangements.

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Our Directors and senior management oversee and manage the overall risks associated with our business operations, including (i) reviewing and approving our risk management policy to ensure that it is consistent with our corporate objectives; (ii) reviewing and approving our corporate risk tolerance; (iii) monitoring the most significant risks associated with our business operation and our management's handling of such risks; (iv) reviewing our corporate risk in the light of our corporate risk tolerance; and (v) monitoring and ensuring the appropriate application of our risk management framework.

Our audit department oversees the obtaining of any requisite governmental pre-approvals or consents, including (i) formulating and updating our regulatory risk management policies; (ii) promulgating regulatory risk management measures; (iii) providing guidance on our risk management approach to the business team; (iv) reviewing internal reporting on key regulatory risks and providing feedbacks; (v) supervising the implementation of our risk management measures in business operations; (vi) reporting to our senior management on our material risks; and (vii) ensuring that the appropriate structure, processes and competences are in place internally. For IP related issues, we have engaged specialized outside IP legal advisers in assisting us in IP matters, such as patent and trademark application and registration matters. We continually review the implementation of our risk management policies and measures to ensure our policies and implementation are effective and sufficient.

Financial Reporting Risk Management

We have in place a set of accounting policies in connection with our financial reporting risk management, such as financial reporting management policies and budget management policies. We have also developed various procedures to implement accounting policies and our finance department reviews our management accounts based on such procedures. In addition, we will provide training to our finance department staff to ensure that they understand our financial management and accounting policies and implement them in our daily operations.

Clinical Data Management

In line with industry practice, we typically collaborate with physicians in local hospitals to conduct clinical trials, which are done primarily by engaging NMPA-certified clinical centers and CROs who meet our requirements, who are responsible for maintaining the confidentiality of the medical records and personal data of subjects enrolled in our clinical trials. We have adopted internal rules requiring our employees to maintain the confidentiality of information related to our clinical trials.

Quality Control Risk Management

Our quality control system is an essential component of our risk management and internal control system. Our quality control measures cover all aspects of our manufacturing operations, including design and construction of manufacturing facilities, the installation and maintenance of manufacturing equipment, procurement of raw materials and packaging materials, quality checks of materials and products, monitoring adverse drug reactions and verification of documentation. The procedures and methodologies of our quality control system are based on GMP standards, the PRC Pharmacopoeia and other applicable domestic and international standards.

Anti-bribery and Anti-corruption

We strictly prohibit bribery or other improper payments in any of our business operations. We keep accurate books and records reflecting transactions and asset dispositions in reasonable details. We will also provide anti-corruption and anti-bribery compliance training periodically to our senior management and employees to enhance their knowledge and compliance with applicable laws and regulations.

Human Resources Risk Management

We formulate our future recruitment plan in light of our current employee structure and our future business plan. We constantly improve our recruitment process with the aid of information technology, such as utilizing online recruitment platforms.

We have employed an independent internal control consultant to conduct an assessment of our internal control system in connection with the [REDACTED]. The internal control consultant has conducted a review procedure on our internal control system in certain aspects for our operations. The internal control consultant conducted its work from May 2021 to July 2021 and provided a number of findings and recommendations in its report. We have subsequently taken remedial actions in response to such findings and recommendations. The internal control consultant performed follow-up assessment on our internal control system from October 2021 to February 2025 and has not identified any material deficiencies in our internal system.