OVERVIEW

Who We Are

We are a commercial-stage biopharmaceutical company. Oncology and hematological diseases are our primary therapeutic areas. Our marketed product, ZEGFROVY® (舒沃哲®), is the world's only small molecule epidermal growth factor receptor ("**EGFR**") tyrosine kinase inhibitor ("**TKI**") approved for the treatment of lung cancer with EGFR exon 20 insertion ("**exon20ins**") mutations, making us the first company in China to discover and develop a first-in-class drug with marketing approval in the United States.

Established in 2017, Dizal was a spin-off from AstraZeneca. Prior to that, we were AstraZeneca global oncology translational science center, Innovative Medicine and Early Development Asia ("**iMED Asia**"). Our competitive strength lies in our strong scientific heritage, complete and intact scientific team with proven track record in drug discovery and development, and practical insights in marketing and commercializing innovative targeted medicines.

Building on our deep expertise in disease knowledge and supported by advanced translational science and drug design platforms, we have developed a robust product portfolio. This includes two approved drugs, namely ZEGFROVY® and golidocitinib, one registrational stage drug candidate, three post-proof-of-concept ("**post-PoC**") assets, and one early clinical stage asset. ZEGFROVY® was launched in China and approved in the United States. It was the first drug invented in China that received Breakthrough Therapy Designations from both the United States FDA and China NMPA for the treatment of lung cancer. It is currently the only small-molecule drug recommended by internationally authoritative National Comprehensive Cancer Network NSCLC Guidelines for the treatment of NSCLC with EGFR exon20ins. Furthermore, it is the only targeted drug included in the China's National Reimbursement Drug List ("**NRDL**") for the treatment of relapsed and refractory ("**r/r**") NSCLC with EGFR exon20ins, as of the Latest Practicable Date. As of the same date, golidocitinib, a next-generation, highly selective Janus kinase 1 ("**JAK1**") inhibitor, is the world's first and only JAK1 inhibitor approved for the treatment of relapsed or refractory peripheral T-cell lymphoma ("**r/r PTCL**"). Recognizing its clinical value, U.S. FDA granted golidocitinib Fast Track and Orphan Drug Designations. Golidocitinib is also included in China NRDL.

Our Origins and Team

In 2017, following a strategic reorganization, iMED Asia was spun off as an independent entity, with AstraZeneca contributing a select portfolio of preclinical assets and the Future Industry Investment Fund providing working capital. As part of this transition, Dr. Zhang Xiaolin (張小林), then the head of the iMED Asia, was appointed as the CEO of the newly established company, Dizal. The rest of the iMED Asia organization became the foundation of our company.

Our team, with working experience from leading multinational companies such as AstraZeneca, BMS, Eli Lilly, MSD, Pfizer, Roche, Sanofi, and BeOne Medicines (formerly known as BeiGene), has a strong and successful track record of designing novel molecules and executing innovative clinical trials. The team made direct contributions to some of the landmark drugs like Iressa® (gefitinib) and Tagrisso® (osimertinib). We are the inventor of the first fully blood-brain barrier ("**BBB**") penetrant lung cancer drug zorifertinib (formerly AZD3759). This discovery, which challenged conventional thinking, was recognized as a "Highly Read Article of 2015" by the American Chemistry Society *Journal of Medicinal Chemistry*.

Our Product Portfolio

We have developed a product portfolio comprising two approved drugs, namely ZEGFROVY® and golidocitinib, one registrational stage drug candidate, three post-PoC stage assets, and one early clinical stage asset. All our programs have clear competitive differentiation and aim to compete globally and serve all major markets. The following table summarizes the development status of our later stage portfolio and upcoming milestones.

Product
Target
Indication (Line of Treatment)
Therapy
IND
Dose Escalation
PoC
Registration Trial
NDA
Approval
Regulatory Designation
Commercial Rights
Upcoming Milestones
ZEGFROVY® (DZD9008)
EGFR
EGFR exon20ins NSCLC
2L/2L+
Monotherapy
WU-KONG6: Single arm
PR (China) BTD (China)
Global
(Approved)
WU-KONG1B: Single arm
PR (US) BTD (US)
(Approved in the US) 3Q2026: EU MAA submission
1L
Monotherapy
WU-KONG28: vs. platinum-containing chemo
BTD (China & US)
2Q2026: Primary readout & CN NDA submission 3Q2026: US NDA & EU MAA submission
Adjuvant
Monotherapy
WU-KONG16/18: vs. placebo
2029: Primary readout
PACC NSCLC
1L
Monotherapy
WU-KONG15/35*: Single arm
2Q2026: Primary readout; Ph3 IND submission
Adjuvant
Monotherapy
WU-KONG16: vs. placebo
2030: Primary readout
WU-KONG18: vs. placebo
2Q2026: Ph3 Initiation
EGFRm NSCLC
1L/2L/2L+
Combo with DZD6008
TIAN-SHAN8: Single arm
3Q2026: Primary readout; 1L Ph3 IND submission
Golidocitinib (DZD4205)
JAK1
PTCL
r/r
Monotherapy
JACKPOT8B: Single arm
PR
(Approved)
JACKPOT8B: Single arm
FTD & ODD (US)
4Q2026: NDA submission
JACKPOT19: vs. investigator's choice
Global
2H2027: Primary readout
1L
Combo with CHOP
JACKPOT53/55*: Single arm
1Q2026: Primary readout; Ph3 IND submission
Non-driver mutation NSCLC
1L
Combo with IO
JACKPOT33*: Single arm
3Q2026: Primary readout; Ph3 IND submission
Primary ITP
r/r
Monotherapy
JACKPOT16: vs. placebo
1H2028: Primary readout; 2H2028: Ph3 IND submission
Birelentinib (DZD8586)
Lyn/BTK
CLL/SLL
2L/2L+
Monotherapy
TAI-SHAN6: vs. investigator's choice
FTD (US)
2H2027: Interim analysis
1L
Combo with BCL2i
TAI-SHAN10: Single arm
3Q2026: Primary readout; 4Q2026: Ph3 submission
DLBCL
r/r
Monotherapy
TAI-SHAN9: Single arm
Global
3Q2026: Study completion
1L/2L/2L+
Combo with chemotherapy
TAI-SHAN12: Single arm
1Q2026: 2L/2L+ Primary readout; Ph3 IND submission (1L combo with R-CHOP)
Primary ITP
2L/2L+
Monotherapy
TAI-SHAN11: Single arm
1H2027: Primary readout; Ph3 IND submission
DZD6008
EGFR (4th Gen TKI)
EGFR NSCLC
1L/2L/2L+
Monotherapy
TIAN-SHAN1/2: Single arm
2Q2026: Primary readout
2L/2L+
Combo with chemotherapy
TIAN-SHAN7: Single arm
Global
2Q2026: Primary readout
1L/2L/2L+
Combo with ZEGFROVY®
TIAN-SHAN8: Single arm
3Q2026: Primary readout; 1L Ph3 IND submission
GW5282
EZH1/2
NHL
r/r
Monotherapy
BEI-DOU1: Single arm
Global
2Q2026: Determining RP2D
Solid Tumors
r/r
Monotherapy
BEI-DOU2: Single arm
3Q2026: Determining RP2D
DZD1516
HER2+
HER2 + BC
2L/2L+
Combo with HER2 ADC
WEN-JI1: Single arm
Global
2H2027: Combination study initiation
DZD2269
A2aR
Solid Tumors
–
Monotherapy and combo
PAN-GU1: Single arm
Global
2H2027: Combination study initiation
China Clinical Trials
Global/overseas Clinical Trials
Market for commercialization
* Denotes IIT trials
IND = Investigational New Drug
NDA = New Drug Application
PR = Priority Review
BTD = Breakthrough Therapy Designation
FTD = Fast Track Designation
ODD = Orphan Drug Designation
MAA = Marketing Authorization Application

Lung cancer

We are advancing a differentiated product portfolio to address a wide range of unmet medical needs in NSCLC, which accounts for 85% of all lung cancer cases. For NSCLC with driver mutations, we prioritize diseases driven by EGFR mutations, especially those with exon20ins mutations and EGFR P-loop αC-helix compressing ("**PACC**") mutations, acquired resistance, and CNS metastasis. Team has long and successful research history and deep expertise in this area. For NSCLC without known driver mutations, we focus on overcoming immunotherapy resistance, especially resistance to anti-PD-(L)1 antibodies.

- ***ZEGFROVY***®, is an innovative EGFR TKI engineered to expand treatment options for patients with historically hard-to-treat mutations, including EGFR exon20ins and PACC. ZEGFROVY® provides a much-needed treatment option for patients with EGFR exon20ins NSCLC, which represents approximately 12% to 15% of the EGFR mutated NSCLC patients have EGFR exon20ins mutations. This patient population has historically faced poor prognosis. No targeted small molecule therapy was available for these patient population before ZEGFROVY®, and commonly used treatment include chemodoublets and TKIs, with objective response rates ("**ORR**") below 20% and median progression-free survival ("**mPFS**") of around six months or less.

  ZEGFROVY® has been approved for treating EGFR exon20ins mutations positive NSCLC patients who have failed front line platinum-containing chemo doublet treatment. ZEGFROVY® has been included in major clinical practice guidelines for EGFR exon20ins NSCLC. In China, it is a Category I recommendation in the CSCO guidelines for previously treated patients EGFR exon20ins NSCLC, and in the United States it is referenced in the NCCN guidelines as a treatment option following prior systemic therapy, making it **the only** small-molecule targeted therapy for EGFR exon20ins NSCLC included in an internationally recognized lung cancer treatment guideline.

  In the first-line treatment, ZEGFROVY® compares favorably to the current standard of care for EGFR exon20ins NSCLC, including a triple-drug intravenous regimen, without chemotherapy or injection-related toxicities. We plan to file for market approval with FDA, NMPA and EMA for first-line treatment of EGFR exon20ins NSCLC in 2026. We are also developing ZEGFROVY® as an adjuvant therapy for EGFR exon20ins NSCLC in ongoing registrational clinical trials.

  Lung cancer with EGFR PACC mutations represent another class of driver mutations, which occurs in approximately 12.5% of all EGFR-mutant NSCLC. As of the Latest Practicable Date, there were no approved targeted therapies specifically for the treatment of EGFR PACC NSCLC. Frequently used therapies include off-label use of approved EGFR TKIs and chemotherapies with only limited efficacy and short duration of response. In WU-KONG35, ZEGFROVY® at a dose of 300 mg once daily demonstrated a compelling confirmed ORR of 71.4% in patients with

EGFR PACC NSCLC. The reported confirmed ORR of firmonertinib in its Phase 1b clinical trial for EGFR PACC NSCLC administered at 240 mg, a dose three times its approved dose for NSCLC with sensitized mutation, was 68.2%. We are developing ZEGFROVY® as a first-line treatment and adjuvant therapy for EGFR PACC NSCLC in ongoing registrational clinical trials. To expedite the development process, we are pursuing Breakthrough Therapy Designation for ZEGFROVY® for this indication.

In addition, we are developing ZEGFROVY® as part of an all-oral, frontline combination therapy with DZD6008 to treat lung cancer patients with classical EGFR mutations (L858R and del19).

The global EGFR exon20ins NSCLC market grew from US$0.7 billion in 2020 to US$1.0 billion in 2024 at a CAGR of 9.0%, and is expected to increase to US$8.0 billion in 2035, representing a CAGR of 20.5% from 2024 to 2035. The global EGFR PACC NSCLC market grew from US$0.9 billion in 2020 to US$1.0 billion in 2024 at a CAGR of 4.1%, and is expected to increase to US$5.6 billion in 2035, representing a CAGR of 16.5% from 2024 to 2035.

- ***DZD6008*** is a fourth-generation EGFR TKI, addressing the significant unmet needs for NSCLC patients who develop resistance to third-generation EGFR TKIs. The current standard of care for these patients is chemotherapy, which offers limited benefit, with patients receiving the therapy achieving an average ORR of 30% to 40%, mPFS of less than six months.

  The next generation EGFR TKI, the fourth generation, must be able to provide additional treatment benefits over the current third generation, represented by Tagrisso®. Specifically, the fourth generation must be able to (i) suppress common activating mutations, resistant double, and triple mutations, with almost equal potencies to avoid the need for overdosing in order to cover all mutation types; (ii) have high wild-type EGFR selectivity to minimize wildtype EGFR related toxicities; (iii) penetrate BBB most efficiently to effectively treat CNS metastases, and (iv) mitigate enhanced sensitivities to cardiotoxicity risks associated with third-generation EGFR TKIs. DZD6008 is the only fourth-generation EGFR TKI with clinical evidence to meet all four definitive criteria.

  As a monotherapy, DZD6008 has demonstrated compelling clinical efficacy in both heavily treated TKI-resistant EGFR-mutant NSCLC patients, as well as treatment naïve EGFR-mutant NSCLC patients. DZD6008's favorable safety profile makes it an ideal backbone for novel combination regimens, which are being actively explored. On the top of the list is DZD6008 in combination with ZEGFROVY® as it offers significant advantages of as a chemo-free regimen minimizing chemo-related toxicities and as an all oral regimen maximizing patients' compliance.

  In addition, we are also exploring DZD6008 in combination with current standard of care and emerging new therapies such as ADCs.

The global EGFR-mutant NSCLC market grew from US$8.1 billion in 2020 to an estimated US$11.0 billion in 2024. It is projected to further expand to US$24.7 billion by 2035, representing a CAGR of 7.7% from 2024 to 2035.

- ***Golidocitinib***, a next-generation, highly selective JAK1 inhibitor, has shown promising clinical efficacy when combined with an anti-PD(L)-1 antibody in NSCLC patients without known driver mutations. Immunotherapy is the current standard of care for these patients but only with modest clinical benefits, especially for those with intermediate PD-L1 expression.

  Clinical evidence from us and others confirms that aberrant activation of the JAK-STAT pathway, often driven by inflammatory cytokines within the tumor microenvironment, may facilitate immune evasion by upregulating PD-L1 expression and reinforcing immunosuppressive signaling programs that contribute to progressive T-cell dysfunction and exhaustion. Accordingly, JAK1 inhibition with golidocitinib may attenuate these pro-PD-L1 and immune-suppressive signals, thereby modulating the tumor microenvironment and potentially restoring antitumor immune activities.

  We are exploring this hypothesis clinically, evaluating golidocitinib's potential in combination with an anti-PD(L)-1 antibody in NSCLC without known driver mutations in an ongoing investigator-initiated trial in China, JACKPOT33. The data of JACKPOT33 will be used to support the IND application of JACKPOT66, a planned registrational Phase 3 clinical trial for NSCLC without known driver mutations.

  The global NSCLC without known driver mutations market grew from US$13.3 billion in 2020 to an estimated US$21.9 billion in 2024. It is projected to further expand to US$41.8 billion by 2035, representing a CAGR of 6.0% from 2024 to 2035.

- ***GW5282*** is a next-generation EZH1/2 (Enhancer of Zeste Homolog 1 and 2) dual inhibitor. EZH2 is a clinically validated target for multiple hematological and solid tumors. Our translational science research showed that inhibiting EZH2 alone could not completely block the pathway as the EZH1, the other closely related gene family member, often compensates EZH2 activity. Approved EZH1-only inhibitors suffer from another deficiency, too short human blood half-life. Consequently, a much higher dose is necessary in order to cover the target, which causes typical high dose-related bone marrow toxicities. GW5282 stands out as a next-generation therapy that addresses the key limitations of these existing EZH2-only inhibitors. GW5282 was designed to inhibit both EZH1 and EZH2 with equal potencies but spare other non-targeting genes. Available clinical data fully validated our molecular design properties, including a longer half-life, improved absorption and oral bioavailability, and much lower bone marrow toxicities. With these improvement, we are able to reduce the patient's pill burden from over 14 pills to just one or two pills daily, enhancing patient compliance. Our strategic focus for this molecule is directed toward solid tumors, including lung cancer, for which we have validated preclinical evidence.

Hematological diseases

In hematological diseases, we are advancing three differentiated late-stage molecules, including golidocitinib, birelentinib and GW5282.

- ***Golidocitinib*** (brand name: 高瑞哲®) has been approved and launched in China for relapsed/refractory peripheral T-cell lymphoma ("**r/r PTCL**"). Patients with PTCL face a dismal prognosis. The only available front-line treatment, CHOP, is a combination regimen of four chemotherapy drugs. There is no standard of care once the disease progresses. The median Overall Survival ("**mOS**") for relapsed and refractory patients is only about 6 months.

  As a first-in-class agent specifically targeting the JAK-STAT signaling pathway in PTCL, golidocitinib represents a novel targeted drug for this disease. It is designed to deliver a differentiated triple-action profile, combining direct antitumor activity with anti-inflammatory effects and immune modulation, with the objective of providing broad and durable clinical benefits for PTCL patients.

  In the registrational Phase 2 study, JACKPOT8, golidocitinib demonstrated strong anti-lymphoma activity in r/r PTCL, with an ORR of 44.3% and a complete response ("**CR**") rate of 23.9%. These response rates compare favorably with current chemotherapies and emerging single-agent targeted agents in this setting, where ORRs have often been below 30%. The observed efficacy supports the potential of golidocitinib to meaningfully improve outcomes in this difficult-to-treat patient population. Based on these favorable clinical results, golidocitinib was approved in China and included as a Category I recommendation in leading Chinese clinical guidelines, specifically Chinese Society of Clinical Oncology ("**CSCO**") 2025 for r/r PTCL. It is also the first and only JAK1 inhibitor worldwide receiving both FDA Fast Track and Orphan Drug designations for r/r PTCL as of the Latest Practicable Date.

  We plan to file an NDA for golidocitinib for r/r PTCL with the FDA in 2026. Beyond r/r PTCL, we are evaluating golidocitinib for first-line treatment in combination with CHOP. In an ongoing IIT in China, JACKPOT55, Go-CHOP regimen (150 mg of golidocitinib every other day + CHOP) demonstrated strong anti-tumor activity in patients with newly diagnosed PTCL. The reported ORR was 94.1% and the complete response ("**CR**") rate was 64.7%. The study is still ongoing with 85% of patients remained on treatment. The longest PFS has exceeded 15 months. Overall safety profile was as manageable with no treatment discontinuations due to TRAEs. Based on these data, the IND application is planned for JACKPOT28, a registrational Phase 3 clinical trial of golidocitinib for the first-line treatment of newly diagnosed PTCL.

  According to CIC, the global PTCL drug market grew from US$0.9 billion in 2020 to an estimated US$1.5 billion in 2024. It is projected to further expand to US$6.0 billion by 2035, representing a CAGR of 13.5% from 2024 to 2035. China market size increased from US$0.3 billion in 2020 to US$0.5 billion in 2024 and expected to reach US$1.7 billion by 2035, reflecting an 12.0% CAGR over the forecast period.

- ***Birelentinib*** is a novel dual inhibitor of lymphocyte-specific protein tyrosine kinase ("**Lyn**") and Bruton's tyrosine kinase ("**BTK**"), designed to completely block both BTK-dependent and BTK non-dependent pathways

  The first and second generation BTK inhibitors, including ibrutinib, acalabrutinib and zanubrutinib, brought tremendous benefits to CLL/SLL patients. Unfortunately, disease progression is inevitable. A mutation at C481 position was identified clinically as the dominant resistance mutation, resulting in enhanced BTK activity and preventing anti-BTK drug binding. Our translational science research discovered another important resistance mechanism based on the paradoxical observation that about half of the relapsed patients with BTK mutations showed diminished BTK activity. Subsequently, the team further identified that these patients' tumors no long rely on BTK pathway (BTK-independent), but Lyn-AKT pathway instead. Birelentinib is designed to simultaneously inhibit both BTK-dependent and BTK-independent B-cell receptor (BCR) signaling pathways to achieve maximal clinical benefits. Through this dual-pathway mechanism, birelentinib is intended to suppress oncogenic BCR signaling and inhibit tumor growth across multiple subtypes of B-NHL. As of the Latest Practicable Date, it was the first and only dual Lyn/BTK inhibitor in clinical development, according to CIC.

  Birelentinib demonstrated its clinical potential quickly in early clinical studies. A pooled analysis from two clinical studies in heavily pretreated patients with chronic lymphocytic leukemia/small lymphocytic lymphoma ("**CLL/SLL**") was selected for oral presentation at both the 2025 American Society of Clinical Oncology ("**ASCO**") meeting and the 18th International Conference on Malignant Lymphoma ("**ICML**"). Based on these results, U.S. FDA granted birelentinib Fast Track Designation in August 2025 for the treatment of r/r CLL/SLL. We have initiated an international multi-center Phase 3 clinical trial of birelentinib for r/r CLL/SLL in September 2025.

  Beyond CLL/SLL, we are exploring Birelentinib's potential in DLBCL. So far, BTK inhibitors have only shown limited clinical efficacy in non-GCB subtype of DLBCL. We hypothesize that incomplete blockade of BCR signaling is the likely reason. By simultaneously inhibiting both BTK and Lyn signaling, birelentinib may overcome these limitations and improve treatment outcomes in r/r DLBCL. This hypothesis was supported by the results from a Phase 2 clinical study evaluating birelentinib monotherapy in r/r DLBCL, TAI-SHAN9, which was presented at the 2025 European Hematology Association ("**EHA**") Congress and the 18th ICML. Significant anti-tumor activities were observed in both GCB and non-GCB DLBCL subtypes.

  We are also developing birelentinib beyond relapsed/refractory settings in combination with BCL2 inhibitor and chemotherapy for the first-line treatment of CLL/SLL and DLBCL, respectively.

According to CIC, the global CLL/SLL drug market grew from US$8.5 billion in 2020 to an estimated US$13.2 billion in 2024. It is projected to further expand to US$41.3 billion by 2035, representing a CAGR of 10.9% from 2024 to 2035. China remains a key growth engine, with market size increasing from US$0.5 billion in 2020 to US$0.7 billion in 2024 and expected to reach US$2.6 billion by 2035, reflecting an 12.1% CAGR over the forecast period. According to CIC, the global DLBCL drug market grew from US$3.3 billion in 2020 to an estimated US$6.0 billion in 2024. It is projected to further expand to US$24.2 billion by 2035, representing a CAGR of 13.5% from 2024 to 2035. China market size increased from US$0.6 billion in 2020 to US$1.2 billion in 2024 and expected to reach US$4.6 billion by 2035, reflecting an 13.1% CAGR over the forecast period.

- ***GW5282*** can significantly reduce H3K27me3 levels in cells and demonstrates strong anti-tumor activity across NHL models in both *in vitro* and *in vivo* preclinical models. GW5282 is currently in Phase 1/2 clinical study to assess its safety, tolerability, pharmacokinetics, and anti-tumor efficacy in patients with r/r NHL in China. Tumor shrinkage was observed at the starting dose of 40mg, twice daily ("**BID**"). At this dose, more than 90% inhibition of the pharmacodynamic marker was achieved. No dose-limiting toxicities were observed up to 120mg, BID.

Other solid tumors

Beyond lung cancer and hematological diseases, we are advancing three differentiated candidate drugs, including GW5282, DZD1516, and DZD2269 for other solid tumors.

- In addition to lung cancer and r/r NHL, we are developing ***GW5282*** for the treatment of other solid tumors, including prostate, ovarian and endometrial cancers.

- ***DZD1516*** is an oral, reversible, and highly selective small-molecule HER2 TKI that addresses some of the most pressing challenges in treating HER2-positive breast cancer, particularly in patients with CNS metastases. By providing a novel mechanism of action and enhanced brain penetration, DZD1516 represents a promising therapeutic approach for patients who have limited treatment options with current therapies.

- ***DZD2269*** is an innovative, highly selective adenosine A2a receptor ("**A2aR**") antagonist. As of the Latest Practicable Date, there were no approved A2aR antagonists globally. A Phase 1 clinical trial of DZD2269 conducted in healthy volunteers demonstrated that DZD2269 can successfully inhibit the activation of these pathways. Importantly, at a dose of 160 mg, no drug-related adverse effects were observed. DZD2269 exhibited favorable safety and tolerability profiles. These early clinical findings support the continued clinical development of DZD2269 for use in oncology and immune diseases, where the A2aR pathway plays a significant role in immune suppression within the TME.

Immune disorders

- We are exploring the therapeutic potential of our existing pipelines for immune disorders. The Lyn/BTK dual-pathway coverage of birelentinib may be beneficial to address immune-mediated diseases such as ITP, where pathogenic autoantibody production by B cells and Fc receptor-mediated platelet destruction by macrophages are driven by BTK- and Lyn-dependent signaling cascades. By targeting both kinases, birelentinib provides a mechanistic rationale for evaluation in ITP. We are assessing birelentinib in an ongoing Phase 2 clinical trial, TAI-SHAN11, for r/r primary ITP in China.

- In addition, we are developing ***golidocitinib*** for the treatment of primary ITP via a distinct mechanism of action. Golidocitinib is a selective JAK1 inhibitor that reduces overactive JAK/STAT cytokine signaling, which can drive immune-mediated platelet destruction and impaired platelet production. By selectively targeting JAK1, it is designed to deliver immunomodulatory benefit while limiting broader JAK inhibition that may be associated with more off-target side effects. We are assessing golidocitinib in an ongoing Phase 2 clinical trial, JACKPOT16, for r/r primary ITP in China.

- In addition to oral capsule, we are developing ***golidocitinib ointment*** for dermatology indications. Golidocitinib ointment is currently under GMP production and GLP toxicology study. We plan to initiate a Phase 1/2 proof-of-concept trial of golidocitinib ointment for mild-to-moderate atopical dermatitis ("**AD**") in 2027.

Integrated Technology Platform for De-Risked and Accelerated R&D

We attribute the strength of our product portfolio to the integrated technology platform that we have continued to strengthen over the eight years since our inception. We operate this platform under a disciplined, hypothesis-driven framework that is applied consistently across programs for precision molecular design and model-informed clinical development. We set clear "Go — No Go" criteria tied to clinical and translational milestones. This approach allows us to invest resources only in programs that show a strong scientific rationale and a realistic opportunity to achieve global first-in-class or best-in-class differentiation.

Integrated platform for precision molecular design and model-informed clinical development

Our integrated technology platform seamlessly connects translational science, precision molecular design, and predictive clinical pharmacology into a unified workflow. In translational science, we leverage a comprehensive library of over 1,500 cell lines, alongside proprietary disease models that best mimic human diseases with defined biological relevance. These models encompass transgenic and driver-mutation validation models, surgical CNS metastasis models with an intact BBB, and a short oral absorption model designed for rapid drug metabolism and pharmacokinetic ("**DMPK**") readouts. By utilizing these robust tools and applying these models to successfully and accurately predict clinical activities, we meticulously validate the intricate relationship between targets and diseases, define a clear candidate drug target profile ("**CDTP**"), and identify and validate predictive biomarkers that guide patient selection, response prediction, and safety monitoring.

As candidates progress, we incorporate model-informed drug development ("**MIDD**") into our predictive clinical pharmacology approach. This approach integrates preclinical data into models of human pharmacokinetics and pharmacodynamics ("**PK/PD**"). These models assist us in designing clinical trials with rational starting doses, focused dose escalation strategies, and dose levels that strike a balance between efficacy and tolerability.

ZEGFROVY® as proof of platform execution and speed

ZEGFROVY®'s discovery and development exemplifies the practical application of this integrated platform. Backed by translational science and validated pharmacological biomarkers, we observed tumor response at the starting dose. We were able to find our Recommended Phase 2 Dose ("**RP2D**") with only 4 dose cycles. This alone shortened clinical development by more than a year. We had clear understanding of the desired balance between molecule structural rigidity and flexibility. This is the key for ZEGFROVY®'s superior efficacy across over 200 different subtypes of exon20ins. Clinical data confirmed our model for target coverage needed to maximize target inhibition while sparing off-target effects. Putting all these together, we were able to achieve market approval within four years after First Subject In ("**FSI**").

Global Clinical Development

We have been committed from the outset to developing medicines for a global patient population and are among the few China-based companies pursuing global development for every pipeline asset. For candidates that achieve proof of concept, we intend to continue development through globally designed trials rather than restricting development to a single region. As a result, our clinical trials span multiple regions, including five continents and nearly 20 countries. Across these programs, we have enrolled around 800 overseas patients under the care of key opinion leaders ("**KOLs**") in major oncology and hematology medical centers worldwide.

For ZEGFROVY®, golidocitinib and birelentinib, we have obtained seven U.S. regulatory designations, including Breakthrough Therapy Designations and other expedited pathway designations, and we have achieved what we believe to be a historic milestone — ZEGFROVY® became the first China-discovered and developed first-in-class drug to receive marketing approval in the United States. These regulatory interactions also underscore our execution capabilities. For example, our new drug application ("**NDA**") submission for ZEGFROVY® in China and the United States received no deficiency notices and the pre-approval inspections for ZEGFROVY® in China and the United States concluded with no findings.

Rapid Commercialization Uptake

We have successfully transitioned into a fully integrated biopharmaceutical company with both development and commercialization capabilities. Our two approved drugs have been included in leading global and Chinese treatment guidelines, as well as China's NRDL. These inclusions have significantly contributed to the rapid market uptake and growing recognition of our approved products among clinicians. Following their respective regulatory approvals, we achieved the first prescription for ZEGFROVY® within four days.

Since the commercial launch of our first product, ZEGFROVY®, in 2023, we have established a strong growth trajectory, generating revenue of RMB91.3 million, RMB310.8 million, RMB285.7 million, and RMB422.1 million from ZEGFROVY® and nil, RMB49.1 million, RMB52.7 million, and RMB164.2 million from golidocitinib in 2023, 2024, the nine months ended September 30, 2024, and 2025, respectively. Moreover, our focus on efficiency has led to a reduction in selling and distribution expenses as a percentage of revenue. We incurred selling and distribution expenses of RMB322.5 million, and RMB423.7 million in the nine months ended September 30, 2024, and 2025, accounting for 95.3%, and 72.3% of our revenue during the same periods, reflecting our improved sales productivity and optimized cost structure.

Looking Ahead

As we look into the future, we intend to advance our approved drugs and clinical-stage assets through key development milestones and to continue exploring new targets in oncology and immunology diseases. In addition, we plan to strengthen our core technological competencies, while continuously enhancing commercialization capabilities to realize the full market potential of our pipeline. We aim to expand global partnerships to unlock the commercial value of our approved and pipeline products. In parallel, we plan to strengthen in-house manufacturing to support scalable supply and improve cost efficiency. Underpinning these efforts, we prioritize attracting, developing, and retaining top-tier talent across R&D, manufacturing, and commercialization to support long-term growth and global expansion.

OUR STRENGTHS

Deep scientific insight and disease knowledge for drug program selection and prioritization

Our ability to generate breakthrough therapies stems from our deep understanding of cancer biology and our capability to translate scientific insight into differentiated molecular designs.

- ***ZEGFROVY®*** is an innovative EGFR TKI launched in China and approved in the United States. Early in our research, we identified a fundamental limitation in available NSCLC therapies: they did not adequately address the structural diversity and conformational complexity of EGFR mutations, particularly exon20ins variants and PACC mutations. Through comprehensive structural and biochemical analysis, we recognized that exon20ins encompass more than 130 distinct variants, which are far more than commonly appreciated in the published literature at that time. This insight guided the purposeful engineering of ZEGFROVY®'s molecular scaffold to balance the flexibility required to accommodate diverse insertion mutations with the rigidity needed for stable receptor binding.

- ***DZD6008.*** We understand that to meet the four definitive criteria for a fourth-generation EGFR TKI, namely be able to (i) suppress common activating mutations, resistant double, and triple mutations, with almost equal potencies to avoid the need for overdosing in order to cover all mutation types; (ii) have high wild-type EGFR selectivity to minimize wild-type EGFR related toxicities; (iii) penetrate BBB most efficiently to effectively treat CNS metastases, and (iv) mitigate cardiotoxicity risks associated with third-generation EGFR TKIs, a fundamentally new chemical structure is required, rather than incremental modification of existing EGFR TKI scaffolds. Accordingly, we applied precision molecular design to derive DZD6008, with the objective of creating a structurally distinct molecule capable of not only addressing complex resistance mutations but also crossing the blood-brain barrier. These features form the structural and mechanistic basis for DZD6008's broad mutation coverage and next-generation profile.

- ***Birelentinib.*** In addition, our understanding of tumor escape mechanisms inspired the creation of birelentinib, a first-in-class dual Lyn/BTK inhibitor. Recognizing that BTK inhibition only often results in therapeutic escape through alternative signaling routes, we designed birelentinib to simultaneously inhibit Lyn and BTK, thereby blocking a broader network of B-cell receptor signaling and potentially extending clinical benefit across multiple B-NHL subtypes where BTK-only inhibition has limited durability.

Taken together, these molecules exemplify our core strength in deriving deep mechanistic insight, translating it into rational molecular design, and ultimately generating differentiated candidates with the potential to address clinically significant unmet needs.

Integrated translational science platform accelerating development and reducing risks

Our research and development efforts are grounded in a strong commitment to translational science, which enables us to accelerate development while reducing overall risk. Our translational science platform strengthens decision-making from target selection through early clinical development by validating target-disease relationship, defining clear candidate drug profile, and identifying biomarkers that guide dosing and trial design. These capabilities help us focus resources on the most promising programs, accelerate optimization, and improve clinical execution efficiency.

- ***Validate targets with clinically relevant models.*** Using a panel of more than 1,500 cell lines across diverse diseases, we noticed that only a few cell lines showed extremely sensitivity to golidocitinib. We further identified that these sensitive cell lines share a common T-cell origin. With these findings, we were able to make a quick and informed decision to prioritize golidocitinib development in peripheral T-cell lymphoma. Five years later, golidocitinib became the only JAK1 inhibitor approved for r/r PTCL as of the Latest Practicable Date. Our transgenic mouse models also confirmed that EGFR exon20ins mutations drive tumor initiation and progression — an insight foundational to the development of ZEGFROVY®.

- ***Define CDTP requirements to accelerate optimization.*** We employ specialized models, including a disease-relevant surgical brain metastasis model that closely mimics natural disease progression and a "short oral absorption" rat model that provides rapid absorption, distribution, and metabolic stability data, to precisely define CDTP requirements and accelerate compound optimization.

- ***Transform well-defined CDTP into optimally engineered molecule.*** Our medicinal chemistry expertise enables us to transform a well-defined CDTP into an optimally engineered molecule. We have demonstrated our ability to achieve the rare and intricate balance between multiple requirements, such as ensuring BBB penetration while maintaining high selectivity for the drug target.

- ***Identify proof-of-mechanism and proof-of-concept biomarkers to guide dosing and trial design early in the development.*** Using proprietary animal models and tumor tissues, we uncover predictive biomarkers that inform treatment strategies, support dose selection, and enable optimized clinical trial designs, as demonstrated by golidocitinib. Combined with model-informed predictions, this approach helps avoid sub-therapeutic starting doses, improves estimation of maximum tolerated dose ("**MTD**") and dose-limiting toxicity ("**DLT**") to streamline dose escalation, and informs dosing frequency through accurate half-life projections to enhance patient convenience and compliance. It also supports proactive assessment of drug-drug interactions ("**DDIs**") and risks in special populations (e.g., hepatic or renal impairment), reducing trial complexity, accelerating enrollment, and saving time and cost. This rigorous scientific process is further bolstered by our predictive clinical pharmacology capability, which utilizes model-informed drug development ("**MIDD**") to generate accurate projections. We consistently predict preclinical pharmacokinetic ("**PK**") parameters, translating these predictions into anticipated clinical PK behavior. This critical guidance aids in dose selection, study design, and the overall clinical development of our drug candidates.

Overall, our integrated approach, which couples pioneering science with predictive and translational tools, leads to validated clinical acceleration and efficiency as evidenced by the clinical development process of ZEGFROVY®. The molecule completed its Phase 1 dose-escalation trial in only four cohorts, starting at a dose that ultimately proved to be the efficacious dose — well below the industry norm of eight to ten cohorts. This rapid timeline demonstrates our platform's clear ability to accelerate the development of drug candidates while strictly maintaining rigorous scientific standards throughout the process.

The average success rate for oncology drugs advancing from Phase 1 to regulatory approval is generally only 3% to 5% globally, underscoring the substantial challenges inherent in developing effective cancer therapies. Approximately half of drug candidates entering Phase 1 do not progress further due to inadequate PK or safety profiles. By combining pioneering science with predictive modeling and translational tools, our integrated approach is designed to identify and address these risks early. As of the Latest Practicable Date, none of our pipeline candidates had failed in clinical development due to poor PK or safety.

Global clinical execution capabilities evidenced by world-class trials

We aim to develop a globally competitive pipeline, and we are one of the few China-based biopharmaceutical companies that conduct global development for every single pipeline asset.

Extensive global clinical trial experience in line with international standards

We have cultivated extensive global clinical trial experience, designing and executing studies in accordance with the highest international standards. Our global footprint is far-reaching, with clinical trials conducted across five continents and nearly 20 countries. This commitment to international development is reflected in our operations with a cumulative overseas enrollment around 800 patients.

Our competitive trial design allows our clinical trials to be internationally comparable in both scale and design with those run by the leading global competitors. We foster a deep connection with the global scientific community. Most of our global trials are led by globally recognized Key Opinion Leaders ("**KOLs**") in their respective fields. This is especially so in lung cancer, where we maintain close relationships with the most prominent internationally recognized experts. This network helps to support our clinical strategy in reflecting the latest scientific consensus.

We have demonstrated our operational efficiency in global execution. For the global registrational trial of ZEGFROVY®, we achieved an average enrollment speed of over ten patients per month with approximately 100 clinical sites versus the over 200 sites typically required by competitors for the same enrollment speed.

Experienced in-house clinical development team ensuring study quality

Our in-house clinical development team consists of highly skilled professionals with extensive experience in multinational corporations ("**MNCs**"), including leaders who have previously managed global studies at AstraZeneca. The expertise offered by our team supports every phase of study design, implementation, and analysis, ensuring high study quality. Our team effectively manages clinical development timelines and works closely with contract research organizations ("**CROs**") to deliver high-quality results in a timely manner.

Proven global success on registration and application

Quality engagement with major regulatory agencies is often a big challenge for young China-based biotech companies. We have demonstrated our regulatory registration and application capabilities with proven global success. Our track record includes obtaining marketing approvals for two products in both China and the U.S. Our marketed and pipeline products, ZEGFROVY®, golidocitinib, and birelentinib, have collectively received seven major U.S. regulatory designations, including Priority Review, Breakthrough Therapy, Fast Track, and Orphan Drug.

Our U.S. NDA submission for ZEGFROVY® was accepted on the first attempt without any major amendments. The FDA praised our quality submission and subsequent responses, which led to approval ahead of the original timeline set by the Prescription Drug User Fee Act ("**PDUFA**"). Additionally, the pre-approval inspection of our clinical studies resulted in zero findings and no Form 483 issues — an exceptional achievement in the industry, showcasing the strong traceability and defensibility of our data and procedures.

Integrated commercialization capabilities elevating scientific leadership into market leadership

Our sales and marketing strength lies in a combination of scientific marketing, rapid pre-launch execution, comprehensive market access strategies, and a high-performance sales team. We leverage our scientific expertise to educate the market on innovative therapies, ensuring rapid product adoption and broad patient access. Additionally, our integrated commercialization approach and focus on efficiency have led to sustained revenue growth and improved sales productivity.

Scientific marketing builds awareness for innovative drugs

For our approved drugs and pipeline products, which feature first-in-class innovative treatments, we recognize the critical need for robust market education, especially since these products require a distinct approach compared to traditional, mature drug markets. Understanding that innovation often involves differentiated therapeutic mechanisms, we have developed a high-caliber commercialization team specifically trained to educate healthcare professionals, patients, and stakeholders about the clinical benefits and data behind our new drugs. Our marketing strategy is deeply rooted in scientific principles, focusing not only on the efficacy and safety of our therapies but also on educating the market about managing adverse events ("**AEs**") and the importance of personalized medicine.

A key part of our strategy is promoting companion diagnostics to improve mutation detection rates. By achieving simultaneous approval of drugs and companion diagnostic ("**CDx**") tool for the U.S. launch in collaboration with a global leader, we provide scientific resources to support healthcare professionals in identifying the right patients for approved companion diagnostic testing, in accordance with applicable product labels and regulatory requirements. In China, we have partnered with leading companies to promote validated next-generation sequencing ("**NGS**") testing, allowing the right patients to be matched to the right therapies.

We focus on data-driven market education, particularly in complex disease areas. Our pre-launch efforts include sophisticated market shaping and professional education to ensure rapid clinical adoption and optimal usage once the product is approved. This proactive approach accelerates the integration of our therapies into clinical practice.

Pre-launch planning and efficient launch execution enables rapid product uptake

We supplement scientific market efforts with meticulous pre-launch preparation, proven launch excellence capabilities and execution strategies for our drug candidates nearing commercialization. In addition, by leveraging our pre-launch strategies, such as scientific exchanges with KOLs and close monitoring of evolving CSCO guidelines, our experienced commercialization team rapidly activated the hospital network post-approval. As a result, our ZEGFROVY® achieved its first prescription within four days of approval, setting an industry record for drugs shipped from external manufacturing facilities.

Comprehensive market access strategies enable broad patient access

We have also established a comprehensive post-launch commercialization approach and payer engagement, ensuring sustained collaboration with healthcare payers alongside robust market access and product uptake strategies. Reflecting our commercialization abilities and market access strengths, as well as its favorable therapeutic potential to satisfy medical needs, golidocitinib achieved same-year NRDL inclusion following its approval, allowing immediate patient access post-launch. Our post-launch commercialization strategies expanded patient access, boosted market penetration, and validated our commercialization strategy amid competitive oncology pricing pressures.

Strong sales and marketing team drives growth and efficiency

As of September 30, 2025, we have established an integrated commercialization team comprising 592 seasoned professionals. In particular, most of them have deep commercialization experience in lung cancer and hematologic oncology, further enabling the specialized academic promotion of our products.

Supported by our integrated commercialization team, we achieved solid sales performance during the Track Record Period. Our revenue increased by 73.2% from RMB338.5 million in the nine months ended September 30, 2024 to RMB586.3 million in the same period in 2025.

Moreover, our focus on efficiency has led to a reduction in selling and distribution expenses as a percentage of revenue. We incurred selling and distribution expenses of RMB322.5 million, and RMB423.7 million in the nine months ended September 30, 2024, and 2025, accounting for 95.3%, and 72.3% of our revenue during the same periods, reflecting our improved sales productivity and optimized cost structure.

Industry leading management and R&D team with global vision and extensive industry experience

We are led by an experienced management team with an exceptional track record in global pharmaceutical innovation. Under the guidance of Dr. Zhang Xiaolin, our Chief Executive Officer, our core leadership comprises seasoned industry veterans from leading multinational pharmaceutical companies, including AstraZeneca, BMS, Eli Lilly, MSD, Pfizer, Roche, Sanofi, and BeOne Medicines (formerly known as BeiGene), each bringing deep expertise in innovative drug discovery, clinical development and commercialization. Their complementary capabilities and international perspectives underpin our corporate strategy and advance our long-term global growth.

- Dr. Zhang has over 25 years of experience in the biopharmaceutical industry and is recognized as an influential figure in China's pharmaceutical innovation landscape. Prior to founding our company, Dr. Zhang served as Global Vice President at AstraZeneca and played a pivotal role in establishing the Innovation Center China and subsequent AstraZeneca's iMED Asia, where he successfully led multiple global R&D collaborations and innovative drug programs.

- Under Dr. Zhang's leadership, our core management team includes senior experts such as Dr. Yang Zhenfan (楊振帆) (Chief Medical Officer), Chen Suqin (陳素勤) (Senior Vice President for Clinical Operations), Dr. Zeng Qingbei (曾慶北) (Chief Scientist), Dr. Tsui Honchung (徐漢忠) (Senior Vice President for Medicinal Chemistry), and Dr. Chang Shih-Ying (張世英) (Head of CMC), most of whom previously held key positions at AstraZeneca and other global pharmaceutical organizations. Collectively, our leadership team has contributed to the successful development and commercialization of several globally recognized therapies, including Iressa®, Tagisso®, AZD2954, AZD3759 and rolapitant. Their extensive experience in cross-border collaboration and regulatory interaction enables us to efficiently advance first-in-class innovations through international development and commercialization.

- Our commercial operations are led by Wu Qingyi (吳清漪), our Chief Commercial Officer, a proven commercial leader with a track record of successful launches of multiple blockbuster drugs across AstraZeneca, Sanofi and BeOne Medicines (formerly known as BeiGene). Backed by her demonstrated ability in team building and commercialization leadership, we have established a competitive commercial organization aligned with our global expansion strategy.

Backed by visionary leadership, an internationally experienced management team, and sustained confidence from top tier global investors, we are well positioned to continue delivering transformative therapies and driving our sustainable global growth.

OUR STRATEGIES

Advance the global development of our pipeline candidates and strengthen our product portfolio

Our pipeline development strategy is centered on maximizing the clinical and commercial value of approved products while accelerating clinical advancement of pipeline assets, capturing synergies across the portfolio, and expanding into new disease areas with high unmet needs to build a broad, differentiated engine for innovation and long-term growth.

We primarily develop targeted therapies — particularly small-molecule drugs — because we believe that (i) we have accumulated competitive advantages in designing small molecule drugs, and (ii) precisely designed small molecules give us better protection through higher technical barriers for competition. In lung cancer, we are advancing a differentiated NSCLC portfolio targeting hard-to-treat EGFR mutations, treatment resistance, and serious complications including CNS metastases where standard therapies fall short. In hematological diseases, we are advancing differentiated targeted therapies with a focus on expanding options and overcoming resistance in hard-to-treat lymphomas.

Maximize the potential value of our approved products

For our approved products, our strategy is to maximize their potential clinical and commercial values by moving them to earlier lines of therapy, expand their indications with an aim to establish them as new standard of care. For **ZEGFROVY®**, we are moving to first-line and adjuvant settings for EGFR exon20ins NSCLC so patients can benefit earlier. Similarly, we are also exploring additional opportunities such as first-line and adjuvant treatment in PACC NSCLC and first-line EGFR-mutant NSCLC in combination with DZD6008. For **golidocitinib**, we intend to pursue first-line treatment for PTCL and expand its potential use by evaluating combinations with immunotherapy in NSCLC without known driver mutations.

Accelerate the clinical development of our pipeline assets

We aim to accelerate the clinical development of our pipeline products. Our focus is on key therapeutic areas, especially lung cancer and hematological diseases, aiming for a broad clinical presence across various indications. We will prioritize resources for pipeline assets nearing commercialization, including birelentinib and DZD6008.

Explore synergies within our pipeline

We will maximally explore potential synergies between our pipeline and approved products through combination therapies within them. We are developing ZEGFROVY® in an all-oral, frontline combination strategy with DZD6008. This combination is designed to be mutually reinforcing that prevent resistance of both drugs.

Selectively expand our R&D efforts into new disease areas with unmet clinical needs

We are committed to exploring new disease areas with significant unmet clinical needs, including **immunology** and **neurodegenerative diseases**. Our preclinical pipeline is grounded in scientific validation, with a focus on advancing high-potential candidates. We are committed to advancing one compound per year into the IND stage over the next two to three years, ensuring a steady stream of new clinical-stage candidates to replenish our product portfolio.

Strengthen our core technological competencies to continue translating basic research into practical applications

We plan to strengthen our technology capabilities through a set of integrated initiatives to improve efficiency and increase the success prospect of innovation.

Invest in AI for drug discovery, design, and development

We plan to invest in AI and expand its use across the full R&D value chain. In discovery, we aim to apply AI to strengthen our understanding of disease biology and target-disease linkage, helping prioritize the most promising targets and mechanisms. In precision molecular design, we plan to use AI-enabled approaches to propose novel chemistry and molecular designs beyond known scaffolds, accelerate hit-to-lead and lead optimization, and improve key properties such as potency and selectivity. In CMC, we aim to apply AI to support synthetic route scouting and optimize scalable routes with a focus on quality, efficiency, and manufacturability. We also plan to use AI to improve submission readiness and regulatory communications.

Advance small-molecule drug discovery with organoid-enabled translational science

We plan to further refine our small-molecule drug discovery platforms by deepening our understanding of tumor biology, driver mutations, and protein structure-function relationships. To strengthen translation from lab to clinic, we aim to incorporate novel technologies such as organoid screening into our discovery workflows. By using biologically relevant models, we aim to improve candidate differentiation and translational confidence, generate stronger evidence on efficacy signals, resistance patterns, and combination potential, and support biomarker exploration, patient stratification, CNS drug delivery, and model-informed early clinical development.

Further enrich our compound libraries and expand lab automation

We plan to further enrich our compound collection libraries to increase diversities and novelties, with the help of AI. In parallel, we aim to strengthen lab automation capabilities by introducing automated workflows for routine and high-throughput experiments, improving data capture, reproducibility, and cycle time.

Collaborate with leading research institutions to access external innovation

We plan to collaborate with leading academic and research institutions globally to tap into external innovation and scientific breakthroughs. These collaborations may include joint research programs, shared technology platforms, and sponsored translational studies. We aim to establish clear governance for project selection, milestone-driven execution, and intellectual property management so that external insights can be converted into internal capabilities and pipeline opportunities efficiently.

Integrate end-to-end R&D process to improve efficiency and success rates

We plan to maximize synergies across the full R&D cycle by integrating our end-to-end system — from target discovery and mechanism validation to clinical execution and CMC. This approach aims to further improve operational efficiency, speed up feedback loop, increase the probability of success for novel programs, and support the continued expansion and global commercialization of our small-molecule oncology pipeline.

Continuously enhance commercialization capabilities to realize market potential of our pipeline assets

We plan to apply data-driven technologies to optimize commercialization operations and improve execution efficiency. By leveraging market intelligence, we aim to allocate our sales force more precisely and tailor engagement to the right hospitals and specialists. We also plan to expand digital and remote interactions so that education and promotion are not limited to face-to-face activities. In addition, we plan to apply data-driven analytics on unmet need, competitive dynamics, and payer and hospital pathways to refine positioning, and develop evidence packages in our marketing process that support guideline inclusion and reimbursement.

We plan to strengthen internal commercialization capability through systematic training programs for our sales force. These programs aim to improve product knowledge, scientific communication, compliance awareness, and execution skills, helping teams translate knowledge and strategy into consistent field performance. By investing in structured onboarding, continuous learning, and practical coaching, we aim to build a strong sales and marketing infrastructure that supports seamless execution from launch planning to broad market delivery.

In addition, as our pipeline advances, we plan to build launch-ready commercialization capabilities well ahead of key regulatory milestones, including scalable supply planning, internal training, field-force readiness, scientific engagement with targeted KOLs, and preparation for physician and patient education, while mapping key hospitals and specialists, strengthening our nationwide marketing and distribution network, and optimizing market access strategies. Supported by value-based pricing, digital tools, and real-world evidence generation, these efforts aim to substantiate the potential clinical value of our pipeline and facilitate rapid, broad and sustained market and patient coverage upon approval.

We plan to adopt a self-built sales model to strengthen our nationwide sales and marketing network. We are committed to expanding and empowering our professional commercial team to cover the entire value chain — marketing, medical affairs, channel management, market access, and business planning and operation — and to reinforce the expertise of our members through systematic training. We will further strengthen academic promotion activities focusing on priority therapeutic areas such as lung cancer and hematologic malignancies, deliver scientific communication to front line clinicians via key academic channels, and continue to deepen our collaboration with leading hospitals and key opinion leaders.

Expand global visibility and partnerships to unlock commercial potential of our approved and pipeline products

We aim to leverage our robust clinical data and growing global academic presence to expand the recognition of our products. By presenting high quality clinical results at top international academic conferences such as ASCO, WCLC, ASH and ICML, we continue to strengthen our scientific visibility worldwide.

In the nearer term, we plan to adopt a flexible collaboration and licensing strategy to realize the global commercial potential of our approved and pipeline products, particularly in major international markets. To accelerate market access and commercialization, we aim to pursue strategic partnerships with leading multinational pharmaceutical companies and leverage their established commercial infrastructure, market expertise, and distribution networks.

Through these collaborations, we aim to structure value-sharing models that may include upfront payments, development and regulatory milestones, and royalties. This approach is intended to generate earlier financial returns while supporting long-term product value creation. By combining our innovation capabilities with partners' global reach, we aim to bring clinically meaningful precision therapies from China to patients worldwide, creating sustainable value for patients, partners, and shareholders.

In the longer term, we will evaluate the development of a small scale, specialized global commercialization team at an appropriate stage, gradually evolving from collaborative operations to independent execution to enhance global market control and maximize long term product value.

Strengthen in-house manufacturing and improve cost efficiency

We will continue to strengthen our in-house manufacturing capabilities to support the global commercialization and supply of our products. By establishing production facilities in China, we aim to achieve self-sufficiency in manufacturing and create a reliable production base for our marketed products and late-stage candidates.

We have constructed a manufacturing facility in Wuxi, Jiangsu, with a GFA of over 35,000 square meters and an annual capacity of around 70 million tablets and 20 million capsules. The facility is designed to comply with the GMP standards of China and the United States and is expected to commence operation in 2027. Once operational, this facility will form an integrated industrial chain covering preclinical research, clinical development and commercial manufacturing, effectively supporting future product scale-up. Through these efforts, we aim to establish a strong manufacturing foundation that supports the steady and high-quality supply of our drugs.

We aim to strengthen coordination with suppliers to ensure a stable supply of APIs and raw materials, maintaining consistent product quality and availability worldwide. We aim to optimize cost efficiency through in-house manufacturing by refining process control, reducing waste, and enhancing material utilization. We anticipate vertical integration to help reduce intermediary costs and improve capital efficiency. We also plan to adopt centralized procurement and strategic partnerships to stabilize costs and ensure a cost-competitive supply chain.

Attract, nurture and retain top-tier talents across R&D, manufacturing and commercialization

A key part of our strategy is to continuously recruit, develop, and retain top talent to support our global execution and commercialization. We will continue to enhance our already strong R&D organization through focused efforts to identify, recruit, develop and retain both internal and external talents across drug discovery, clinical operations, and translational medicine. Beyond R&D, we are expanding teams in global marketing, medical affairs, and manufacturing quality control to support product launches and drive rapid sales growth.

To nurture the next generation of talent, we focus on fostering a supportive environment where emerging talents are given opportunities to learn from experienced mentors. By providing robust training programs, leadership development initiatives, and clear career paths, we help our newer team members build the expertise needed to eventually step into critical roles, ensuring a smooth transition of knowledge and leadership.

To build a stable and innovative team, we plan to implement a multi-level talent incentive system with long-term benefits. We aim to promote an open and inclusive culture that encourages innovation, allowing our team to thrive and contribute to our ongoing growth and global impact.

OUR PRODUCT PORTFOLIO

Our product portfolio consists entirely of in-house developed small-molecule innovative drugs with global rights. We are strategically focused on oncology indications and hematological diseases. We develop all our products through a coordinated, global approach.

As of the Latest Practicable Date, our product portfolio included (i) two products with marketing authorizations, namely (a) ZEGFROVY®, an innovative EGFR TKIs launched in China and approved in the United States, and (b) golidocitinib, a next-generation, highly selective JAK1 inhibitor approved and launched in China, (ii) one registrational-stage drug candidate, namely birelentinib, (iii) three post-PoC stage assets, namely DZD6008, GW5282, DZD1516 and (iv) one early clinical stage asset, namely DZD2269. The pipeline chart below summarizes the development status of our later stage portfolio and upcoming milestones.

Product
Target
Indication (Line of Treatment)
Therapy
IND
Dose Escalation
PoC
Registration Trial
NDA
Approval
Regulatory Designation
Commercial Rights
Upcoming Milestones
ZEGFROVY® (DZD9008)
EGFR
EGFR exon20ins NSCLC
2L/2L+
Monotherapy
WU-KONG26: Single arm
WU-KONG31B: Single arm
PR (China)
BTD (China)
PR (US)
BTD (US)
Global
(Approved)
(Approved in the US)
3Q2026: EU MAA submission
1L
Monotherapy
WU-KONG28: vs. platinum-containing chemo
BTD (China & US)
2Q2026: Primary readout & CN NDA submission
3Q2026: US NDA & EU MAA submission
Adjuvant
Monotherapy
WU-KONG16/18: vs. placebo
2029: Primary readout
PACC NSCLC
1L
Monotherapy
WU-KONG15/35*: Single arm
2Q2026: Primary readout; Ph3 IND submission
Adjuvant
Monotherapy
WU-KONG16: vs. placebo
2030: Primary readout
WU-KONG18: vs. placebo
2Q2026: Ph3 Initiation
EGFRm NSCLC
1L/2L/2L+
Combo with DZD6008
TIAN-SHAN8: Single arm
3Q2026: Primary readout; 1L Ph3 IND submission
Golidocitinib (DZD4205)
JAK1
PTCL
r/r
Monotherapy
JACKPOT8B: Single arm
PR
(Approved)
JACKPOT8B: Single arm
FTD & ODD (US)
4Q2026: NDA submission
JACKPOT19: vs. investigator's choice
2H2027: Primary readout
1L
Combo with CHOP
JACKPOT53/55*: Single arm
1Q2026: Primary readout; Ph3 IND submission
Non-driver mutation NSCLC
1L
Combo with IO
JACKPOT33*: Single arm
3Q2026: Primary readout; Ph3 IND submission
Primary ITP
r/r
Monotherapy
JACKPOT16: vs. placebo
1H2028: Primary readout; 2H2028: Ph3 IND submission
Birelentinib (DZD8586)
Lyn/BTK
CLL/SLL
2L/2L+
Monotherapy
TAI-SHAN6: vs. investigator's choice
FTD (US)
2H2027: Interim analysis
1L
Combo with BCL2i
TAI-SHAN10: Single arm
3Q2026: Primary readout; 4Q2026: Ph3 submission
DLBCL
r/r
Monotherapy
TAI-SHAN9: Single arm
3Q2026: Study completion
1L/2L/2L+
Combo with chemotherapy
TAI-SHAN12: Single arm
1Q2026: 2L/2L+ Primary readout; Ph3 IND submission (1L combo with R-CHOP)
Primary ITP
2L/2L+
Monotherapy
TAI-SHAN11: Single arm
1H2027: Primary readout; Ph3 IND submission
DZD6008
EGFR (4th Gen TKI)
1L/2L/2L+
Monotherapy
TIAN-SHAN1/2: Single arm
2Q2026: Primary readout
EGFR NSCLC
2L/2L+
Combo with chemotherapy
TIAN-SHAN7: Single arm
2Q2026: Primary readout
1L/2L/2L+
Combo with ZEGFROVY®
TIAN-SHAN8: Single arm
3Q2026: Primary readout; 1L Ph3 IND submission
GW5282
EZH1/2
NHL
r/r
Monotherapy
BEI-DOU1: Single arm
2Q2026: Determining RP2D
Solid Tumors
r/r
Monotherapy
BEI-DOU2: Single arm
3Q2026: Determining RP2D
DZD1516
HER2+
HER2 + BC
2L/2L+
Combo with HER2 ADC
WEN-JI1: Single arm
2H2027: Combination study initiation
DZD2269
A2aR
Solid Tumors
–
Monotherapy and combo
PAN-GU1: Single arm
2H2027: Combination study initiation
China Clinical Trials
Global/overseas Clinical Trials
Market for commercialization
* Denotes IIT trials
IND = Investigational New Drug
NDA = New Drug Application
PR = Priority Review
BTD = Breakthrough Therapy Designation
FTD = Fast Track Designation
ODD = Orphan Drug Designation
MAA = Marketing Authorization Application

We generated revenue of RMB91.3 million, RMB359.9 million, RMB338.5 million, and RMB586.3 million from sales of our marketed products, ZEGFROVY® and golidocitinib, in 2023, 2024, and the nine months ended September 30, 2024 and 2025, respectively. Set forth below are the respective revenue contributions of each of these launched products in each year/period of the Track Record Period.

	For the year ended December 31,				For the nine months ended September 30,			
	2023		2024		2024		2025	
	RMB'000	*%*	*RMB'000*	*%*	*RMB'000*	*%*	*RMB'000*	*%*
					(Unaudited)			
ZEGFROVY®	91,289	100.0	310,805	86.4	285,746	84.4	422,094	72.0
Golidocitinib	–	–	49,096	13.6	52,705	15.6	164,207	28.0
Total	**91,289**	**100.0**	**359,901**	**100.0**	**338,451**	**100.0**	**586,301**	**100.0**

ZEGFROVY® — A Globally Competitive, Commercialized EGFR TKI

Overview

ZEGFROVY® (舒沃哲®) is an innovative, highly selective EGFR TKI independently discovered and developed by us for the treatment of NSCLC. ZEGFROVY® was designed to address key limitations of existing EGFR TKIs, which showed only limited activity against structurally complex EGFR alterations, particularly EGFR exon 20 insertion mutations and EGFR P-loop α and C-helix compressing ("**PACC**") mutations. These mutations alter the conformation of the EGFR kinase domain, impair the binding of conventional inhibitors, and result in limited therapeutic options and suboptimal outcomes for affected patients. On top of that, these mutations are highly heterogenous. A successful drug has to be able to inhibit most, if not all, mutation subtypes to bring meaningful clinical benefits to the patient population.

To overcome these challenges, we designed ZEGFROVY® as a potent small-molecule inhibitor capable of broadly and durably inhibiting both classical EGFR driver mutations and hard-to-treat variants such as exon20ins and PACC mutations. It is designed to recognize and engage diverse, altered three-dimensional structures and steric features of mutant EGFR kinase domains, enabling sustained inhibitory activity while other TKIs cannot do. Through the combined optimization of molecular selectivity, inhibitory potency, and pharmacokinetic properties, ZEGFROVY® is being developed as a targeted therapy capable of delivering meaningful clinical benefits across a broad spectrum of EGFR-mutant NSCLC.

In its multinational registrational clinical study, WU-KONG1B, and China standalone multicenter registrational study, WU-KONG6, ZEGFROVY® demonstrated anti-tumor efficacy across multiple mutation subtypes, together with a favorable safety profile and a long half-life, supporting its potential as a best-in-class therapy. Results from WU-KONG1B were selected

for oral presentation at the 2025 World Conference on Lung Cancer ("**WCLC**") and at the 2024 American Society of Clinical Oncology ("**ASCO**") meeting and were published in the leading scientific *Journal of Clinical Oncology*. Results from WU-KONG6 were published in *Lancet Respiratory Medicine*.

ZEGFROVY® received marketing approvals from the NMPA in August 2023 and from the U.S. FDA in July 2025 for the treatment of adult patients with locally advanced or metastatic NSCLC harboring EGFR exon20ins mutations who have previously received platinum-containing chemotherapy. According to CIC, ZEGFROVY® is **the first** innovative, first-in-class drug discovered and developed in China with marketing approval in the United States. It is also **the first** drug that received Breakthrough Therapy Designations in both the United States and China for lung cancer. Furthermore, it was **the only** second- or later-line treatment for EGFR exon20ins NSCLC included in the NRDL, as of the Latest Practicable Date.

ZEGFROVY® has been well recognized by the global scientific and medical communities and included in major clinical practice guidelines. In China, it is a Category I recommendation in the CSCO guidelines for previously treated patients, and in the United States it is referenced in the NCCN guidelines as a treatment option following prior systemic therapy, making it **the only** small-molecule targeted therapy for EGFR exon20ins NSCLC included in an internationally recognized lung cancer treatment guideline as of the Latest Practicable Date.

We are expanding the development of ZEGFROVY® beyond second- or later-line therapy. In June 2025, we completed enrollment for WU-KONG28, a multinational registrational Phase 3 clinical trial evaluating ZEGFROVY® as a first-line treatment for EGFR exon20ins NSCLC across 16 countries and regions, including China, the United States and Europe. We expect a data readout for WU-KONG28 in the second quarter of 2026. The study will also serve as the post-approval confirmatory trial required under the China and U.S. accelerated approval framework.

In parallel, we are evaluating ZEGFROVY® as an adjuvant therapy in patients with EGFR exon20ins or PACC NSCLC in WU-KONG16, a registrational Phase 3 clinical trial in China. In addition, we are developing ZEGFROVY® as part of an all-oral, frontline combination therapy with DZD6008 for patients with classical EGFR mutations.

We generated revenue of RMB91.3 million, RMB310.8 million, RMB285.7 million, and RMB422.1 million from sales of ZEGFROVY® in 2023, 2024, and the nine months ended September 30, 2024 and 2025, respectively. ZEGFROVY® was promptly included into the NRDL in China with coverage effective since January 2025, reflecting the level of clinical and regulatory recognition it has received.

Drug Design and Mechanism of Action

EGFR is a receptor tyrosine kinase that regulates one of the most fundamental signaling pathways governing cellular growth, differentiation, and survival. Under normal physiological conditions, EGFR activation is tightly controlled by extracellular ligands such as EGF, AREG,

and TGF-α. Ligand binding induces receptor dimerization and activation of the intracellular kinase domain, which in turn triggers downstream signaling cascades that regulate normal cellular functions and proliferations.

Genetic alterations in EGFR, commonly occurring in exons 18 to 21 that encode the tyrosine kinase domain, can disrupt this tightly regulated process. Certain EGFR mutations result in ligand-independent activation of the receptor, leading to continuous autophosphorylation and persistent downstream signaling. As a result, tumor cells harboring these mutations gain a growth advantage through enhanced proliferation, impaired apoptosis and sustained oncogenic signaling. Classical driver mutations, such as exon 19 deletions and exon 21 L858R point mutation, are generally sensitive to conventional EGFR TKIs.

However, approximately 12% to 15% of EGFR mutations are exon20ins mutations, and these represent a distinct clinical challenge because they generally do not respond well to conventional EGFR TKIs. Exon20ins mutations alter the spatial conformation of the EGFR kinase domain in a manner that limits the binding affinity of traditional TKIs, resulting in reduced efficacy and limited treatment options for patients. EGFR TKIs specifically designed to target exon20ins mutations, such as ZEGFROVY®, can engage the altered kinase pocket and effectively inhibit aberrant autophosphorylation, thereby suppressing downstream oncogenic signaling pathways.

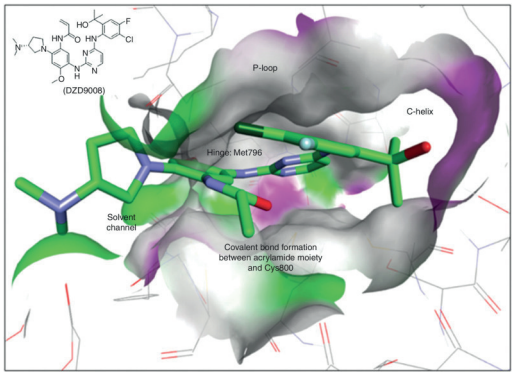
Approximately 12.5% of EGFR mutations are PACC mutations, which are characterized by compression of the phosphate-binding loop and the αC-helix. These structural alterations narrow the ATP-binding pocket and disrupt the binding of conventional EGFR TKIs, resulting in intrinsic resistance to available therapies and leaving patients without approved targeted treatment options. ZEGFROVY® is designed to accommodate this compressed and reshaped kinase pocket and to maintain inhibitory activity despite the altered conformation. By effectively inhibiting mutant EGFR autophosphorylation under these structural conditions, ZEGFROVY® suppresses downstream proliferative and survival signaling and promotes tumor cell death.

At the same time, wild-type EGFR plays an essential role in normal tissues, and excessive inhibition of non-mutated EGFR can lead to dose-limiting toxicities. Accordingly, a key challenge in EGFR-targeted drug development is achieving potent inhibition of mutant EGFR while minimizing activity against wild-type EGFR. ZEGFROVY® was designed with this objective in mind, aiming to provide selective suppression of oncogenic EGFR signaling while maintaining a favorable therapeutic window.

At the molecular level, ZEGFROVY® forms a bidentate interaction between its aminopyrimidine group and the Met796 residue in the hinge region of the EGFR kinase domain, stabilizing target engagement. In addition, its acrylamide group forms an irreversible covalent bond with Cys800 of the EGFR protein, thereby locking the compound in place and preventing kinase activation. The 2-hydroxypropan-2-yl group occupies a region adjacent to

the αC-helix, while the dimethylaminopyrrolidine group interacts with solvent-exposed residues, further enhancing binding affinity and inhibitory activity. Collectively, these interactions enable ZEGFROVY® to achieve potent and selective inhibition of mutant EGFR signaling.

Binding of ZEGFROVY® to the EGFR kinase pocket



Source: Mengzhao Wang et al. Cancer Discovery. 2022

Monotherapy for exon20ins NSCLC

ZEGFROVY® received marketing approvals from the NMPA in August 2023 and from the U.S. FDA in July 2025 for treating EGFR exon20ins mutations positive NSCLC patients who have failed front line platinum-containing chemo doublet treatment. It has been recommended in the CSCO (China clinical guideline) and NCCN (U.S. clinical guideline) for the treatment of previously treated EGFR exon20ins NSCLC.

We are expanding the clinical development of ZEGFROVY® towards first-line treatment. In June 2025, we completed enrollment for WU-KONG28, a multinational registrational Phase 3 clinical trial evaluating ZEGFROVY® vs. platinum containing chemo doublet in treatment naïve EGFR exon20ins NSCLC. It is being conducted across 16 countries and regions, including China, the United States and Europe. We expect to obtain primary data readout for WU-KONG28 in the second quarter of 2026.

Market Opportunities and Competitive Landscape

According to CIC, there are approximately 2.5 million new cases of lung cancer globally each year, with NSCLC being the most common type, accounting for about 85% of the new cases. Among NSCLC patients, EGFR driver mutations represent a major molecular subset, with an overall prevalence of approximately 30% globally and over 50% in China. Among EGFR-mutant NSCLC patients, approximately 12% to 15% of patients carry exon20ins mutations.

For NSCLC patients with EGFR exon20ins who have failed front line treatment, previous treatment options include first- to third-generation EGFR TKIs, chemotherapy, and immunotherapy. For these patients, platinum-containing chemotherapy as well as TKIs delivered only modest responses and short disease control, underscoring a large gap versus classic EGFR mutations where targeted therapy is highly effective. There remains a substantial unmet clinical need for more effective and reliable treatment options in the second- or later-line setting.

In the first-line setting, clinical guideline recommendations include platinum-containing chemo doublet, or amivantamab (an intravenously administered cMet/EGFR bispecific antibody) with platinum-containing doublet chemotherapy. Amivantamab with chemo doublet, a triple-drug intravenous regimen, showed an ORR of 67% and an mPFS of 11.4 months, representing an improvement over platinum-containing chemotherapy alone. However, the need for repeated intravenous infusions, chemotherapy-associated toxicities and cumulative treatment burden may limit long-term tolerability and adherence. Accordingly, there remains an unmet need for effective, convenient and chemotherapy-free targeted therapies for first-line treatment of EGFR exon20ins NSCLC.

The global EGFR exon20ins NSCLC market grew from US$0.7 billion in 2020 to US$1.0 billion in 2024 at a CAGR of 9.0%, and is expected to increase to US$8.0 billion in 2035, representing a CAGR of 20.5% from 2024 to 2035.

As of the Latest Practicable Date, in addition to ZEGFROVY®, there was one targeted therapy approved for EGFR exon20ins NSCLC globally, namely Rybrevant® (amivantamab-vmjw) developed by Johnson & Johnson.

For details, see "Industry Overview — The Oncology Therapeutics Market — The EGFR Exon20ins NSCLC Market."

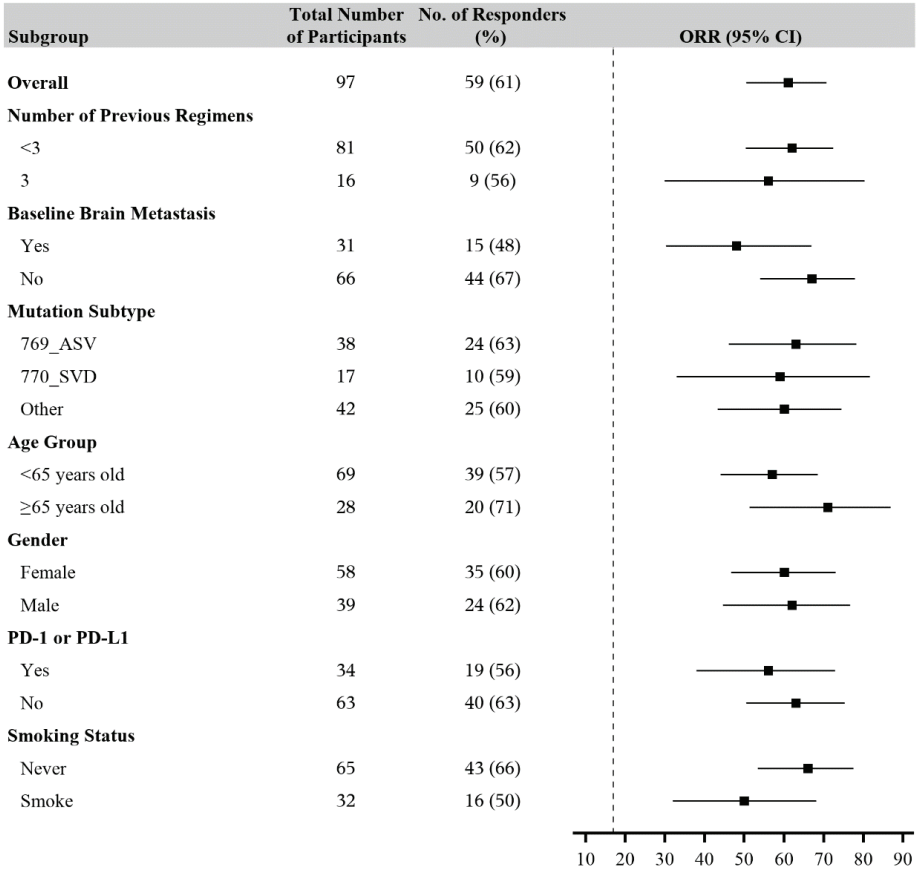
Competitive Advantages

Superior clinical efficacy in the second- or later-line setting

High tumor response rate. In the registrational Phase 2 WU-KONG6 trial conducted in China, ZEGFROVY® achieved a confirmed ORR of 61% in patients with locally advanced or metastatic EGFR exon20ins NSCLC. Rybrevant® (amivantamab-vmjw), an intravenously administered bispecific antibody developed by Johnson & Johnson and a commonly used therapy in this setting, reported an ORR of 40% in its registrational study in a similar patient population. No head-to-head comparisons were conducted between ZEGFROVY® and Rybrevant®.

In addition, ZEGFROVY®'s efficacy is consistent across treatment line, mutation subtype, age, sex, previous immunotherapy and smoking status subgroups, as illustrated in the figure below.

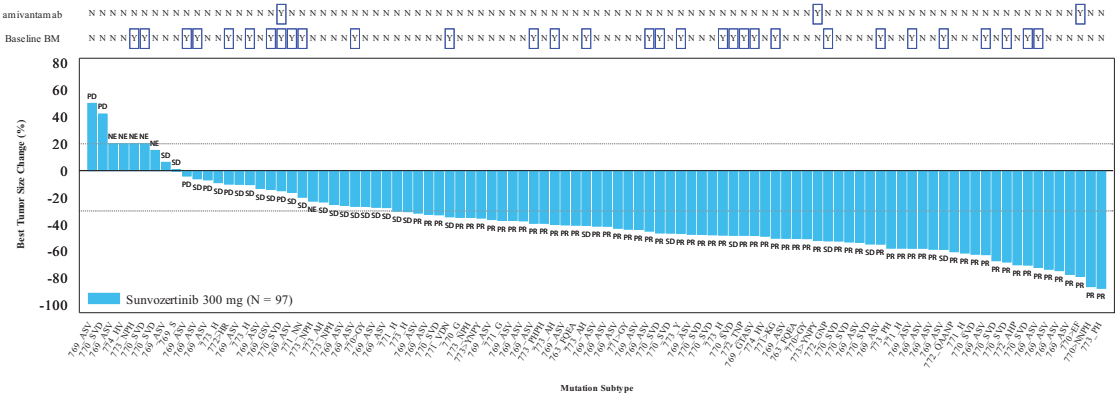
Subgroup analysis of ORR in WU-KONG6



Source: Published data of WU-KONG6 on Lancet Respiratory Medicine 2024

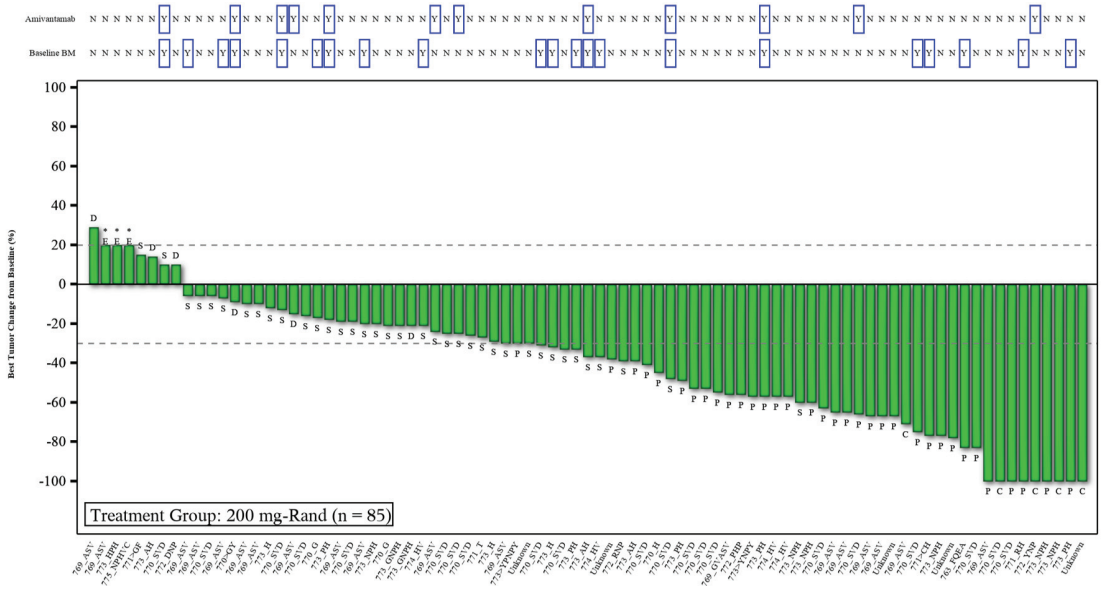
Consistent activity across exon20ins subtypes. As illustrated in the below waterfall plots, ZEGFROVY® demonstrated consistent anti-tumor activity across multiple exon20ins subtypes in the China registrational Phase 2 trial WU-KONG6 and the global registrational Phase 2 clinical trial WU-KONG1B.

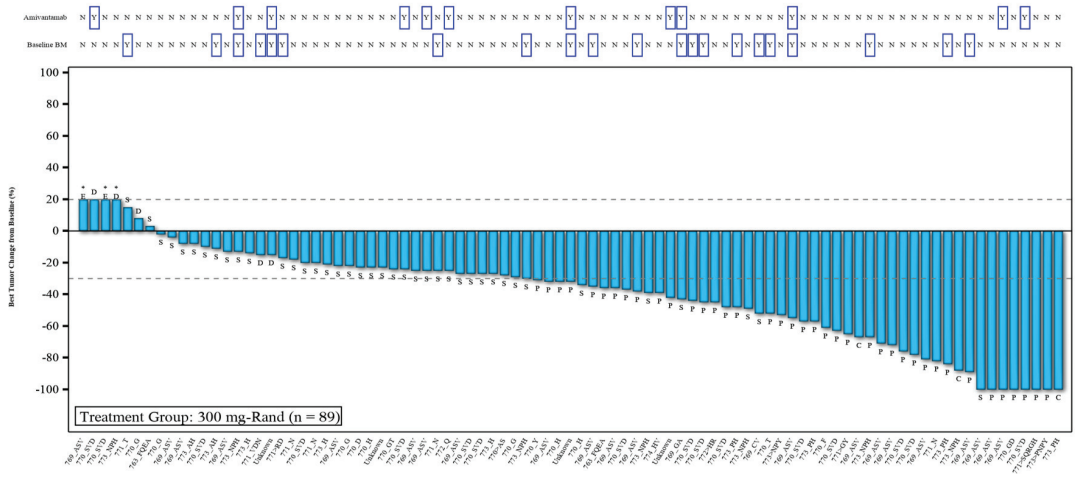
Waterfall plot of best tumor size change of target lesions across mutation subtypes of WU-KONG6



Source: Published data of WU-KONG6 on Lancet Respiratory Medicine 2024

Waterfall plot of best tumor size change of target lesions across mutation subtypes of WU-KONG1B





Source: Published data of WU-KONG1B on World Conference on Lung Cancer 2025

Given the substantial heterogeneity of exon20ins mutations and the variability in drug sensitivity across insertion sites, the breadth and consistency of activity observed with ZEGFROVY® supports its potential applicability across a wider range of patient subgroups.

Potential for sequential therapy. In a subset analysis, ZEGFROVY® achieved a 67% ORR in patients who had previously progressed on Rybrevant® (amivantamab). These findings indicate that ZEGFROVY® may retain clinical activity following treatment with another exon20ins-targeted agent, supporting its potential role in treatment sequencing and highlighting its differentiated mechanism of action.

Clinically meaningful activity in CNS metastases. A *post hoc* analysis of intracranial response in WU-KONG1B study showed a confirmed intracranial ORR of 40% in patients with measurable brain lesions. This signal is clinically meaningful, as CNS metastases are a common and difficult-to-treat complication in advanced NSCLC and frequently drive morbidity and disease progression. These results suggest that ZEGFROVY® may have the potential to provide both systemic and intracranial disease control.

Encouraging signs of efficacy in the first-line setting

Pooled analysis from WU-KONG1 and WU-KONG15 studies showed promising anti-tumor activity of ZEGFROVY® in first-line setting of advanced EGFR exon20ins NSCLC, with a confirmed ORR of 78.6% and an mPFS of 12.4 months. These findings, which were reported in the 2023 European Society for Medical Oncology ("**ESMO**") Annual Meeting, support the potential for ZEGFROVY® to deliver meaningful clinical benefits as a first-line monotherapy while preserving the convenience and tolerability advantages as an oral targeted therapy.

A chemotherapy-free first-line option avoiding the complexity and toxicity of combination chemotherapy

In contrast to combination chemotherapy and antibody-based regimens, ZEGFROVY® offers a once-daily oral monotherapy option for first-line treatment. This approach may reduce treatment burden, avoid toxicities associated with cytotoxic chemotherapy, and improve patient convenience and adherence. A chemotherapy-free regimen is particularly attractive for older and frail patients who are less tolerable to treatment associated toxicities.

Convenient once-daily oral administration

ZEGFROVY® exhibits a relatively long half-life of approximately 50 hours in humans and a flat pharmacokinetic profile characterized by modest peak-to-trough variability. These properties support once-daily oral dosing and provide practical advantages over intravenous therapies such as antibody-based regimens. Oral administration eliminates the need for infusion center visits, reduces treatment burden for patients and caregivers, and may improve adherence and quality of life in real-world settings.

High selectivity for mutant EGFR with a favorable safety profile

Preclinical data demonstrate that ZEGFROVY® strongly inhibits exon20ins EGFR while showing substantially weaker inhibition of wild-type EGFR. ZEGFROVY® exhibits a 3- to 50-fold selectivity for mutant EGFR over wild-type EGFR, outperforming the selectivity reported for another small-molecule EGFR inhibitor, mobocertinib ("**TAK-788**"). This high selectivity prolife supports a wider therapeutic window in clinical settings and reduces the likelihood of toxicities commonly associated with wild-type EGFR inhibition.

Clinically, ZEGFROVY® has demonstrated a manageable safety and tolerability profile. Adverse events were generally manageable with standard supportive care or dose modification, allowing most patients to remain on treatment. Given oncologists' familiarity with EGFR TKI-associated toxicities, the safety profile supports the integration of ZEGFROVY® into routine clinical practice.

Summary of Clinical Trials and Development Plan

The following table sets forth an overview of the completed and ongoing registrational clinical trials of ZEGFROVY® as a monotherapy treatment for exon20ins NSCLC.

Study Name	Indication	Line of Treatment	Trial Phase	Trial Status	Primary Regions	Start Date	Completion Date/ Planned Data Readout Date
WU-KONG1 . . .	Advanced EGFR exon20ins NSCLC	2L/2L+	Registrational Phase 1/2	Completed	China, North America, Europe and South America	November 2021	October 2024
WU-KONG6 . . .	Advanced EGFR exon20ins NSCLC	2L/2L+	Registrational Phase 2	Completed	China	July 2021	April 2023
WU-KONG28 . .	Advanced EGFR exon20ins NSCLC	1L	Registrational Phase 3	Ongoing	China, North America, Europe and South America	December 2022	Primary readout in 2Q 2026

WU-KONG1

This is a global registrational Phase 1/2, open-label, multicenter study to assess the safety, tolerability, pharmacokinetics and anti-tumor efficacy of ZEGFROVY® in patients with advanced NSCLC with EGFR or HER2 mutations. Results from this clinical trial supported the accelerated approval of ZEGFROVY® in the United States.

Trial design. The study included Part A and Part B. **Part A** was a Phase 1 study that, included dose escalation, food effect and dose expansion. **Part B** (WU-KONG1B) was a Phase 2, registrational study. WU-KONG1B included two cohorts: 200 mg (cohort 1) and 300 mg (cohort 2). Eligible patients were randomized to receive ZEGFROVY® treatment at 200 mg or 300 mg once daily, until objective disease progression, intolerable toxicities, patient withdrew, or other discontinuation criteria met.

Trial objectives. The primary objective of WU-KONG1B was to evaluate anti-tumor efficacy of ZEGFROVY® using independent review committee ("**IRC**") assessed confirmed overall response rates ("**cORRs**") as the primary endpoint in previously treated patients with locally advanced or metastatic NSCLC harboring EGFR exon20ins. The secondary objectives were to assess anti-tumor efficacy using other efficacy endpoints (IRC assessed duration of response ("**DoR**") as key secondary endpoint), safety and tolerability, as well as PK.

Trial status. We initiated this registrational Phase 1/2 trial in November 2021 and completed this trial in October 2024.

Efficacy results. A total of 202 patients with advanced EGFR exon20ins NSCLC were enrolled. Of these, 91 patients were initially assigned to the 200 mg cohort, and 93 patients to the 300 mg cohort. After determining the optimal recommended phase 2 dose ("**RP2D**") of 300 mg, 18 additional patients were enrolled into the 300 mg cohort, resulting in 111 patients in the 300 mg group.

The efficacy analysis included 85 patients from the 200 mg randomization cohort (200 mg-rand), 89 from the 300 mg randomization cohort (300 mg-rand), and 107 from the 300 mg overall cohort (300 mg-all), who met predefined criteria. According to the IRC, most patients showed tumor size reduction in their target lesions. The cORRs were 45.9%, 47.2%, and 45.8% in the 200 mg-rand, 300 mg-rand, and 300 mg-all cohorts, respectively. The null hypothesis was rejected with statistical significance (p<0.0001). The following table sets forth the tumor responses of patients in each cohort in this trial.

Tumor response assessed by the IRC

Tumor Response	200 mg-Rand (N = 85)	300 mg-Rand (N = 89)	300 mg-All (N = 107)
Objective Response Rate, n (%)	39 (45.9)	42 (47.2)	49 (45.8)
97.5% CI[a]	(33.6-58.5)	(35.1-59.5)	(34.8-57.0)
p-value[b]	<0.0001	<0.0001	<0.0001
Disease Control Rate, n (%)	76 (89.4)	82 (92.1)	95 (88.8)
97.5% CI[a]	(79.6-95.6)	(83.3-97.2)	(80.1-94.6)
Best Overall Response, n (%)			
Complete Response	5 (5.9)	3 (3.4)	3 (2.8)
Partial Response	34 (40.0)	39 (43.8)	46 (43.0)
Stable Disease	37 (43.5)	40 (44.9)	46 (43.0)
Progressive Disease	6 (7.1)	5 (5.6)	8 (7.5)
Not Evaluable	3 (3.5)	2 (2.2)	4 (3.7)

Note: Tumor assessment followed RECIST 1.1.

Abbreviations: IRC, independent review committee; ORR, objective response rate.

a Based on the Clopper-Pearson exact CI method for a single binomial proportion.

b The one-sided P value against a null hypothesis of ORR ≤17% was calculated based on Simon's two-stage method for the 300 mg-all group, and the binomial exact test was used for other treatment groups.

Source: Published data of WU-KONG1B on Journal of Clinical Oncology 2025

At both doses, tumor response was observed regardless of various factors, although the 200 mg group showed more variability in the cORRs. Non-Asia patients with baseline brain metastasis, and those previously treated with amivantamab showed higher cORRs at 300 mg compared to 200 mg.

A *post hoc* evaluation of intracranial response showed 40% cORRs in patients with measurable intracranial lesions. The estimated median DoR was 11.1, 13.8, and 9.8 months in the 200 mg-rand, 300 mg-rand, and 300 mg-all cohorts, respectively.

Safety results. Relative dose intensities were 99.3% for the 200 mg dose and 84.4% for the 300 mg dose. TRAEs of Grade 3 or above were reported in 40.7% and 58.6% of patients in the 200 mg and 300 mg groups, respectively. Serious adverse events ("**SAEs**") were reported in 17.6% and 23.4% of patients in these groups.

At the 200 mg and 300 mg doses, TRAEs leading to dose interruption, reduction, and discontinuation were reported in 35.2% vs. 49.5%, 23.1% vs. 38.7%, and 4.4% vs. 7.2% of patients, respectively. No fatal TRAEs were reported.

The most common treatment-related SAEs (≥2%) included diarrhea (0% vs. 8.1%), pneumonia (2.2% vs. 1.8%), anemia (2.2% vs. 0.9%), and rash (2.2% vs. 0.9%). Dose discontinuation due to TRAEs occurred in a few patients, with one patient from the 200 mg group discontinuing treatment due to diarrhea.

ZEGFROVY® showed a tolerable and acceptable safety profile at 300 mg once daily. The most common TEAEs were diarrhea (87.4%), increased blood CPK (53.2%), anemia (47.7%), rash (47.7%), and vomiting (44.1%). Most of these TEAEs were grade 1 or 2 in severity and manageable with dose adjustments and supportive care. Hepatic safety concerns were minimal, and no cases of Hy's law were identified. Renal toxicity risk was low, and the incidence of interstitial lung disease ("**ILD**") and pneumonitis was 1.8% and 2.7%, respectively, similar to other EGFR inhibitors. No fatal case of ILD was reported.

WU-KONG6

This is a registrational Phase 2, single-arm, multicenter study to evaluate the anti-tumor efficacy, safety, tolerability and pharmacokinetics of ZEGFROVY® in patients with locally advanced or metastatic NSCLC harboring EGFR exon20ins mutations in China. Results from this clinical trial supported the marketing approval of ZEGFROVY® in China.

Trial design. In this registrational Phase 2 trial, eligible patients were enrolled and received ZEGFROVY® at 300 mg once daily, until objective progressive disease, intolerant or other discontinuation criteria met.

Trial objectives. The primary objective of WU-KONG6 was to evaluate the anti-tumor efficacy of ZEGFROVY® using ORR assessed by independent review committee ("**IRC**") according to RECIST 1.1 as the primary endpoint.

The secondary objectives were to assess anti-tumor efficacy using other variables (investigator assessed ORR, investigator and IRC assessed DoR, PFS, and OS), to assess the safety, tolerability and PK of ZEGFROVY®.

Trial status. We initiated this registrational Phase 2 trial in July 2021 and completed this trial in April 2023.

Efficacy results. Between July 19, 2021, and May 6, 2022, 104 patients were enrolled in the study. As of the data cutoff on October 17, 2022, the last enrolled patient had been followed up for approximately 6 months.

As set forth in the table below, among 97 patients who were evaluated for efficacy, 59 (61%) achieved a tumor response, resulting in a cORR of 61%.

Tumor response in WU-KONG6

	Number of participants (n=97)
Best tumor response, n (%)	
Complete response	0 (0%)
Partial response	59 (61%)
Stable disease	26 (27%)
Progressive disease	6 (6%)
Not evaluable	6 (6%)
Confirmed ORR (%), (95% CI)	61% (50-71)
p value	< 0.0001
Disease control rate (%), (95% CI)	88% (79-93)

Note: Tumour response is shown, as assessed according to RECIST 1.1 by the independent review committee. ORR=objective response rate. CI: confidence interval; IRC: independent review committee; ORR: objective response rate.

Source: Published data of WU-KONG6 on Lancet Respiratory Medicine 2024

Tumor responses were observed regardless of factors such as age, sex, smoking history, EGFR exon20ins subtypes, baseline brain metastasis, previous treatments, or history of onco-immunotherapy. In subset analysis, ZEGFROVY® showed a 67% ORR in patients who had previously progressed on amivantamab.

Safety results. ZEGFROVY® was well tolerated at 300 mg once daily. The most common Grade 3 or above TRAEs included increased blood creatine phosphokinase (17%), diarrhea (8%), and anemia (6%). The most common serious TRAEs included interstitial lung disease (5%), anemia (3%), vomiting (2%), nausea (2%), and pneumonia (2%).

WU-KONG28

This is a global registrational Phase 3, open-label, randomized, multicenter study of ZEGFROVY® versus doublet platinum-containing chemotherapy as first-line treatment for patients with locally advanced or metastatic NSCLC harboring EGFR exon20ins mutations. The study will also serve as the post-approval confirmatory trial required under the accelerated approval framework.

Trial design. In this Phase 3 trial, eligible patients were randomized to receive ZEGFROVY® (300 mg once daily) or doublet platinum-containing chemotherapy in a 1:1 manner, stratified by baseline brain metastasis. Participants randomized into ZEGFROVY® treatment arm continued on ZEGFROVY® treatment until treatment discontinuation criteria met. Participants may continue to receive the above treatment beyond RECIST 1.1 defined progression as long as they continue to show clinical benefit, as judged by the investigator and agreed by sponsor physician.

Participants randomized into chemotherapy arm can receive up to 6 cycles of intravenous infusion of chemotherapy as the initial treatment. Participants whose disease has not progressed after 4 cycles of first-line doublet platinum-containing chemotherapy may receive pemetrexed maintenance monotherapy until treatment discontinuation criteria met and continue on the treatment beyond disease progression as long as they show clinical benefit, as judged by investigator and agreed by sponsor physician.

Trial objectives. The primary objective of WU-KONG28 is to assess the anti-tumor efficacy of ZEGFROVY® versus doublet platinum-containing chemotherapy in patients with newly diagnosed or treatment naïve NSCLC carrying EGFR exon20ins using PFS as assessed by blinded independent central review ("**BICR**") per RECIST 1.1 as the primary endpoint.

The secondary objective included: (i) to assess anti-tumor efficacy using other parameters, include OS (key secondary endpoint), PFS by investigator assessment, ORR, DoR, and DCR, (ii) to characterize the safety and tolerability of ZEGFROVY® versus chemotherapy, and (iii) to assess the PK profile of ZEGFROVY® and metabolite(s) in patients receiving ZEGFROVY®.

Trial status. We initiated this registrational Phase 3 trial in December 2022. We completed enrollment for this trial in June 2025. We expect to obtain primary readout for this trial in the second quarter of 2026.

Monotherapy for PACC NSCLC

In addition to EGFR exon20ins mutation, we are expanding the development of ZEGFROVY® to NSCLC harboring EGFR PACC mutations. These mutations represent a structurally distinct class of EGFR alterations and are frequently associated with intrinsic resistance to currently available EGFR TKIs.

Market Opportunities and Competitive Landscape

Approximately 12.5% of EGFR mutations are PACC mutations. These mutations span exons 18 to 21 and disrupt the relative orientation of the P-loop and αC-helix, resulting in compression of the ATP-binding pocket. This altered conformation substantially impairs the binding of conventional EGFR TKIs and limits their inhibitory activity, leaving patients with EGFR PACC NSCLC with limited therapeutic options.

As of the Latest Practicable Date, there were no approved targeted therapies specifically indicated for the treatment of EGFR PACC NSCLC. As a result, therapies available for patients with these mutations, including many marketed EGFR TKIs, are typically associated with modest efficacy and limited durability of response.

The global EGFR PACC NSCLC market grew from US$0.9 billion in 2020 to US$1.0 billion in 2024 at a CAGR of 4.1%, and is expected to increase to US$5.6 billion in 2035, representing a CAGR of 16.5% from 2024 to 2035.

As of the Latest Practicable Date, in addition to ZEGFROVY®, there were three drug candidates under clinical development for EGFR PACC NSCLC globally.

For details, see "Industry Overview — The Oncology Therapeutics Market — The EGFR PACC NSCLC Market."

Competitive Advantages

Encouraging early clinical efficacy in EGFR PACC NSCLC

In WU-KONG35, ZEGFROVY® at a dose of 300 mg once daily demonstrated a compelling confirmed ORR of 71.4% in patients with EGFR PACC NSCLC. The reported confirmed ORR of firmonertinib in its Phase 1b clinical trial for EGFR PACC NSCLC administered at 240 mg, a dose three times its approved dose for NSCLC with sensitized mutation, was 68.2%. Although no head-to-head comparisons were conducted, these findings highlight the potential of ZEGFROVY® to deliver clinically meaningful efficacy in this difficult-to-treat patient population.

Summary of Clinical Trials and Development Plan

The following table sets forth an overview of the ongoing and planned clinical trials of ZEGFROVY® as monotherapy for EGFR PACC NSCLC.

Study Name	Indication	Line of Treatment	Trial Phase	Trial Status	Region	Start Date	(Planned) Data Readout Date
WU-KONG15 . .	Advanced EGFR PACC NSCLC	1L	IIT[1]	Ongoing	China	November 2021	Primary readout in 2Q 2026
WU-KONG35 . .	Advanced EGFR PACC NSCLC	1L	IIT[1]	Ongoing	China	March 2025	Primary readout in 2Q 2026
WU-KONG8 . . .	Advanced EGFR PACC NSCLC	1L	Registrational Phase 3	Planned	China	1H 2027	Primary readout in 2H 2028

Note:

1. *The data of WU-KONG15 and WU-KONG35 investigator-initiated trials ("IITs") will be used to support the IND application for WU-KONG8, the registrational Phase 3 clinical trial for advanced EGFR PACC NSCLC.*

WU-KONG15 and WU-KONG35

Trial design. WU-KONG15 is an investigator-initiated trial of ZEGFROVY® in patients with locally advanced or metastatic NSCLC harboring EGFR mutations, including PACC mutations, initiated by a leading public hospital in Beijing. A total of 8 cohorts are planned in WU-KONG15 study, and among them, cohort 8 intends to enroll 20-30 treatment naïve patients with advanced NSCLC carrying EGFR PACC mutations. Patients will receive ZEGFROVY® 200 mg once daily, until disease progression, intolerable AE, or other discontinuation criteria met.

WU-KONG35 is an investigator-initiated trial of ZEGFROVY® in treatment-naïve patients with advanced NSCLC harboring uncommon EGFR mutations, including PACC mutations, initiated by a leading public hospital in Shanghai. A total of 34 patients are planned to be enrolled, and will receive ZEGFROVY® treatment at the doses of 200 mg (N=14) or 300 mg (N=20) until disease progression, unacceptable toxicity, withdrawal of informed consent, initiation of other anti-tumor treatments, death, or other discontinuation of treatment as deemed by the investigator, whichever occurred first.

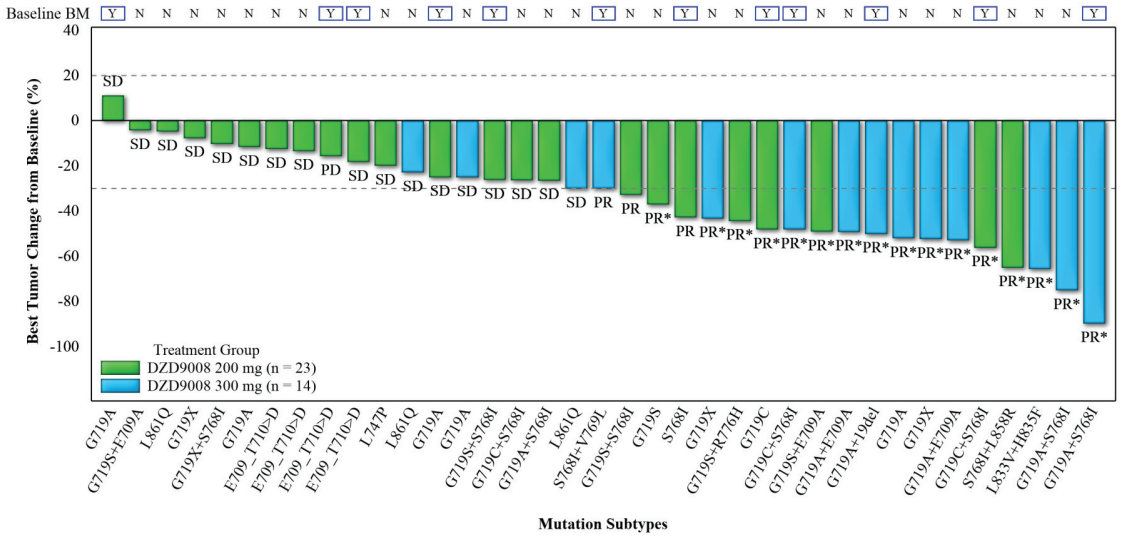
Trial objectives. The primary objective of WU-KONG15 and WU-KONG35 is to assess anti-tumor efficacy of ZEGFROVY® using PFS (WU-KONG15) and ORR (WU-KONG35) assessed by investigator as the primary endpoint. The secondary objectives were to assess anti-tumor efficacy of ZEGFROVY® (using DoR, DCR, and OS as endpoints), safety and tolerability of ZEGFROVY®, using AE and SAE as the endpoints.

Trial status and plan. WU-KONG15 was initiated in November 2021 and WU-KONG35 was initiated in March 2025. We obtained initial data readout for both trials in December 2025 and reported the results at the J.P. Morgan Healthcare Conference 2026. We expect to obtain further trial data with more patients and longer follow-up time in the second quarter of 2026. The data of WU-KONG15 and WU-KONG35 trials will be used to support the IND application for WU-KONG8, a planned registrational Phase 3 clinical trial for advanced EGFR PACC NSCLC.

Efficacy data as of December 2025. As of December 2025, ZEGFROVY® at a dose of 300 mg once daily demonstrated a confirmed ORR of 71.4% in patients with EGFR PACC NSCLC. The waterfall comparison indicates that the 300 mg cohort achieved better overall response and deeper tumor shrinkage than the 200 mg cohort. Anti-tumor activity was observed across EGFR PACC/uncommon mutation subtypes, including single and complex mutations, and notable tumor responses were also observed in patients with baseline non-radiated brain metastasis.

The waterfall plot below shows each patient with best percentage change from baseline in tumor target lesion size, comparing the 200 mg and 300 mg dose groups (200 mg n=23; 300 mg n=14).

Waterfall Plot of Best Change in Tumor Size of Target Lesions (200 mg vs. 300 mg)



Note: PR: Partial Response; SD: Stable Disease (Non-CR/Non-PD); PD: Progressive Disease; BM: Brain Metastasis; n: Number of participants in the analysis set with best change in tumor size.

*Unconfirmed best overall response was displayed in the plot, * was a confirmed response.*

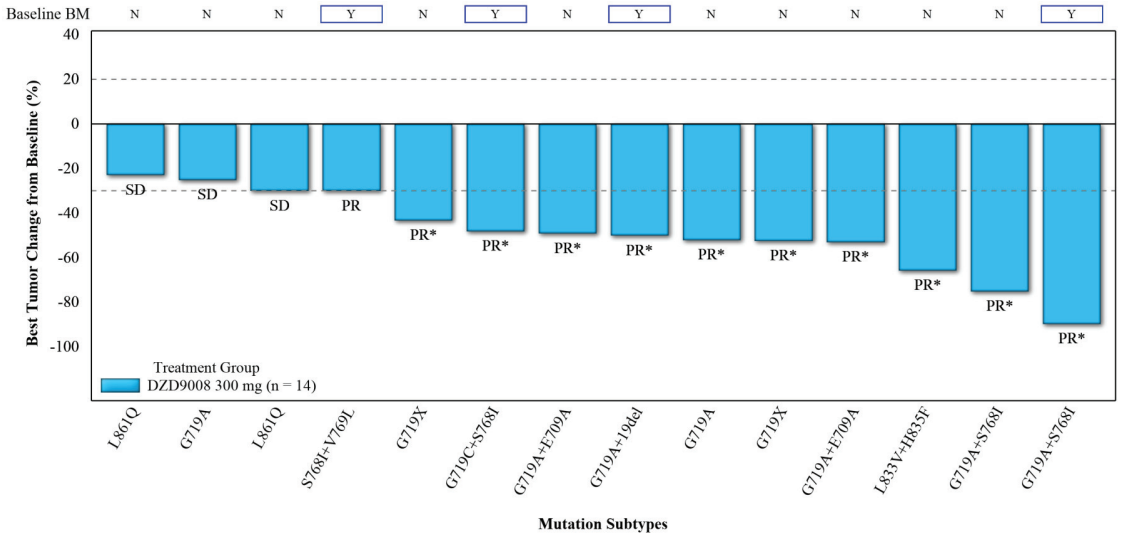
*Best change from baseline (%) in tumor size is defined as {(smallest sum of diameters of the target lesions among all assessed points post baseline - sum of diameter at baseline) / sum of diameter at baseline} *100.*

Positive values indicate tumor growth; on the contrary, negative values indicate tumor reduction. Dashed line represents the threshold for progressive disease (20%) and partial response (-30%).

Source: Presentation at J.P. Morgan Healthcare Conference 2026

The combined waterfall and swimmer plot below presents the 300 mg cohort by showing each patient with best percentage change from baseline in tumor target lesion size and the corresponding treatment duration and response status over time.

Waterfall and Swimmer Plot of Tumor Response and Treatment Duration (300 mg Cohort)

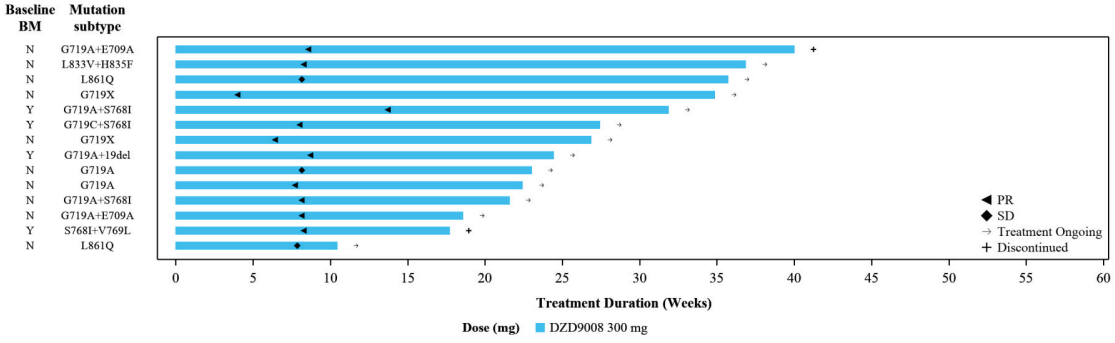


Note: PR: Partial Response; SD: Stable Disease (Non-CR/Non-PD); PD: Progressive Disease; BM: Brain Metastasis; n: Number of participants in the analysis set with best change in tumor size.

*Unconfirmed best overall response was displayed in the plot, * was a confirmed response.*

*Best change from baseline (%) in tumor size is defined as [(smallest sum of diameters of the target lesions among all assessed points post baseline - sum of diameter at baseline) / sum of diameter at baseline] *100.*

Positive values indicate tumor growth; on the contrary, negative values indicate tumor reduction. Dashed line represents the threshold for progressive disease (20%) and partial response (-30%).



Note: PR: Partial Response; SD: Stable Disease (Non-CR/Non-PD); BM: Brain Metastasis.

Unconfirmed best overall response was displayed in the plot.

Source: Presentation at J.P. Morgan Healthcare Conference 2026

WU-KONG8

WU-KONG8 is planned as a registrational Phase 3, randomized, open-label, multicenter trial of ZEGFROVY® versus doublet platinum-containing chemotherapy as first-line treatment for patients with locally advanced or metastatic NSCLC harboring EGFR PACC or L861Q mutations in China.

Trial plan. We plan to initiate this trial in the first half of 2027 following the IND approval.

Adjuvant Therapy for EGFR Exon20ins and PACC NSCLC

Adjuvant therapies are administered following curative-intent treatment, such as surgery, with the objective of eliminating residual microscopic disease and reducing the risk of recurrence. The development of ZEGFROVY® across EGFR exon20ins and PACC NSCLC is supported by the central role of EGFR signaling in both disease initiation and treatment resistance. ZEGFROVY®'s oral administration, targeted mechanism of action, and activity across structurally diverse EGFR alterations support its evaluation across multiple stages of disease and consistent with the evolving paradigm of extending targeted EGFR inhibition earlier and more broadly to improve durable clinical outcomes.

The following table sets forth an overview of the ongoing and planned clinical trials of ZEGFROVY® as an adjuvant therapy for exon20ins and PACC NSCLC.

Study Name	Indication	Trial Phase	Trial Status	Primary Regions	(Planned) Start Date	(Planned) Data Readout Date
WU-KONG16 . .	Stage Ib to IIIA EGFR exon20ins and PACC NSCLC	Registrational Phase 3	Ongoing	China	December 2025	Primary readout for EGFR exon20ins NSCLC in 2029; for EGFR PACC NSCLC in 2030
WU-KONG18 . .	Stage Ib to IIIA EGFR exon20ins and PACC NSCLC	Registrational Phase 3	Planned	North America, Europe and China	Q2 2026	Primary readout for EGFR exon20ins NSCLC in 2030; for EGFR PACC NSCLC in 2031

WU-KONG16

This is a registrational Phase 3, double-blind, randomized, placebo-controlled, multicenter clinical study with investigator-assessed disease-free survival as the primary endpoint to evaluate anti-tumor efficacy and safety of ZEGFROVY® versus placebo as adjuvant therapy in patients with stage IB to stage IIIA NSCLC harboring EGFR exon20ins or EGFR PACC mutations after surgery, with or without adjuvant doublet platinum-containing chemotherapy in China.

Trial design. This study plans to enroll approximately 360 participants, including 180 harboring EGFR exon20ins (cohort 1) and 180 harboring EGFR PACC mutations (cohort 2). Within each cohort, participants will be stratified by postoperative pathological tumor stage (IB, II or IIIA) and randomized in a 1:1 ratio to receive ZEGFROVY® (200 mg once daily) or placebo (once daily). The participants will receive oral administration of ZEGFROVY® or placebo following randomization, in 21-day cycles, until meeting any treatment discontinuation criteria (objective disease recurrence, intolerable AE, completion of 3-year (156-week) treatment period, study termination, death, treatment or study withdrawal by participants, whichever occurs first).

Trial objectives. The primary objective of WU-KONG16 is to assess anti-tumor efficacy of ZEGFROVY® versus placebo using DFS assessed by investigator as the primary endpoint. The secondary objectives included: (i) to assess the anti-tumor efficacy using other variables, including DFS rate at 2, 3, 5 years, OS and OS rate at 2, 3, 5 years, (ii) to assess safety and tolerability, and (iii) to assess the PK of ZEGFROVY® and its metabolite(s).

Trial status. We initiated this registrational Phase 3 trial in December 2025 and expect to obtain primary readout for EGFR exon20ins NSCLC patients in 2029 and for EGFR PACC NSCLC in 2030.

WU-KONG18

WU-KONG18 is planned as a global registrational Phase 3, double-blind, randomized, placebo-controlled, multicenter study to assess the efficacy and safety of ZEGFROVY® versus placebo as adjuvant therapy in patients with stage IB-IIIA NSCLC harboring EGFR exon20ins mutations who have had radical surgery, regardless of adjuvant chemotherapy.

Trial design. This trial plans to enroll approximately 250 participants with stage IB (high-risk) to stage IIIa NSCLC and harboring EGFR exon20ins mutations. Eligible participants will be enrolled and stratified by postoperative pathological tumor stage (IB/II/IIIA), receipt of adjuvant chemotherapy and randomized in a 1:1 ratio to receive ZEGFROVY® (200 mg once daily) or placebo (once daily). The participants will receive oral administration of ZEGFROVY® or placebo following randomization, in 21-day cycles, until meeting any treatment discontinuation criteria (including objective disease recurrence, intolerable AE, completion of 3-year treatment period, study termination, death, treatment or study withdrawal by participants, whichever occurs first).

Trial objectives. The primary objective of WU-KONG18 is to assess anti-tumor efficacy of ZEGFROVY® versus placebo using DFS assessed by investigator as the primary endpoint. The secondary objectives included: (i) to assess the anti-tumor efficacy using other variables, including DFS rate at 2, 3, 5 years, OS and OS rate at 2, 3, 5 years, (ii) to assess safety and tolerability, and (iii) to assess the PK of ZEGFROVY® and its metabolite(s).

Trial plan. We obtained the approval from the U.S. FDA for this trial in July 2025. We plan to initiate this trial in the second quarter of 2026 and expect to obtain primary readout for EGFR exon20ins NSCLC in 2030 and for EGFR PACC NSCLC in 2031.

Combination Therapy with DZD6008 for NSCLC with Classical EGFR mutations

In addition to monotherapy, we are advancing ZEGFROVY® as part of an all oral, frontline combination regimen with DZD6008 for the treatment of NSCLC with classical EGFR mutations. DZD6008 is a novel, highly selective, fourth-generation EGFR TKI. For additional information, see "— Our Product Portfolio — DZD6008, a novel, highly selective, fourth-generation EGFR TKI."

This combination is designed to be mutually reinforcing and to mitigate the emergence of resistance of ZEGFROVY® and DZD6008. Together, the regimen is designed to create a high barrier to resistance by targeting complementary escape pathways, with the aim of delivering more durable clinical benefit and potentially establishing a differentiated standard of care in the first-line setting. This all-oral combination is currently in active clinical development and reflects our strategic focus on addressing resistance as means to meaningfully extend treatment durability.

The following table sets forth an overview of the ongoing and planned clinical trials of ZEGFROVY® in combination with DZD6008 for the treatment of NSCLC with classical EGFR mutations.

Study Name	Indication	Line of Treatment	Trial Phase	Trial Status	Region	(Planned) Start Date	(Planned) Data Readout Date/ NDA Submission Date
TIAN-SHAN8 . .	Advanced EGFR-mutant NSCLC	2L/2L+	Phase 1/2	Ongoing	China	July 2025	Primary readout in 3Q 2026
TIAN-SHAN16 .	EGFR-mutant NSCLC	1L	Registrational Phase 3	Planned	China	1H 2027	NDA submission in 2029

TIAN-SHAN8

This is a Phase 1/2, open-label, multicenter study to assess the safety, tolerability, pharmacokinetics, and anti-tumor efficacy of ZEGFROVY® in combination with DZD6008 in locally advanced or metastatic NSCLC patients with classical EGFR mutations in China.

Trial design. This study includes Part A (dose escalation) and Part B (dose expansion).

In Part A, locally advanced or metastatic NSCLC patients with classical EGFR mutations following at least one line of prior EGFR TKI regimen will be enrolled, to receive DZD6008 in combination with ZEGFROVY® treatment. Two combination dose cohorts are planned. The starting dose of DZD6008 and ZEGFROVY® are 40 mg and 100 mg once daily, respectively. Bayesian optimal interval ("**BOIN**") design will be utilized to inform the dose escalation/de-escalation. Following completion of the dose-limiting toxicity ("**DLT**") assessment period for each dose cohort, data will be reviewed by a safety review committee ("**SRC**") to determine the subsequent dose escalation scheme.

Part B will be initiated upon emerging data from Part A. Eligible patients with locally advanced or metastatic NSCLC with classical EGFR mutations will be enrolled to receive DZD6008 in combination with ZEGFROVY® treatment at selected combination dose(s).

Trial status. We initiated this Phase 1/2 trial in July 2025 and expect to obtain primary readout for this trial in the third quarter of 2026.

TIAN-SHAN16

TIAN-SHAN16 is a registrational Phase 3, randomized, open-label, multicenter study of DZD6008 combined with ZEGFROVY® as first-line treatment in NSCLC patients with classical EGFR mutations. We plan to initiate this trial in the first half of 2027.

Golidocitinib — A Commercialized, Next-generation, Highly Selective JAK1 Inhibitor

Overview

Golidocitinib (brand name: 高瑞哲®) is a next-generation, oral, highly selective JAK1 inhibitor for the treatment of hematological diseases and for solid tumors without known driver mutations. It was approved by the NMPA in China in June 2024 for the treatment of adult patients with relapsed/refractory peripheral T cell lymphoma ("**r/r PTCL**"). In addition, golidocitinib has been granted Fast Track Designation and Orphan Drug Designation by the U.S. FDA for the treatment of r/r PTCL, supporting its continued global clinical development. As of the Latest Practicable Date, golidocitinib was the **first and only** JAK1-specific inhibitor approved for a T-cell lymphoma indication, according to CIC.

Golidocitinib is designed to selectively inhibit JAK1-mediated signaling pathways that play a central role in the pathogenesis of PTCL, while minimizing inhibition of other JAK family members that are more closely associated with off-target toxicities. It demonstrates 200- to 400-fold selectivity for JAK1 over other members of JAK family, allowing it to avoid the anemia-related adverse effects that may arise from inhibiting Janus kinase 2 ("**JAK2**") pathway.

The clinical results for golidocitinib have been presented at numerous international academic conferences, including oral presentations or poster sessions at the 2025 European Hematology Association ("**EHA**") Congress and the 2025 International Conference on Malignant Lymphoma ("**ICML**"). Research findings have also been published in internationally recognized journals such as *Lancet Oncology* and *Annals of Oncology*. In addition, golidocitinib has received clinical recognition through inclusion in the CSCO Lymphoma Treatment Guidelines with a Category I recommendation for the treatment of r/r PTCL.

In addition to r/r PTCL, we are evaluating golidocitinib's potential in combination with chemotherapy for the first-line treatment of PTCL. For solid tumors, golidocitinib has also shown promising clinical efficacy when combined with an anti-PD(L)-1 antibody in NSCLC without known driver mutations. Moreover, we are developing golidocitinib for the treatment of primary immune thrombocytopenia ("**ITP**").

Beyond oral capsule, we are developing golidocitinib ointment for dermatology indications. Golidocitinib ointment is currently under GMP production and GLP toxicology study. We plan to initiate a Phase 1/2 proof-of-concept trial of golidocitinib ointment for mild-to-moderate atopical dermatitis ("**AD**") in 2027.

We generated revenue of nil, RMB49.1 million, RMB52.7 million, and RMB164.2 million from sales of golidocitinib in 2023, 2024, and the nine months ended September 30, 2024 and 2025, respectively. Golidocitinib was included in the NRDL in China with coverage effective January 2025.

Drug Design and Mechanism of Action

The JAK/STAT pathway is a central role in intracellular signaling cascade that mediates cytokine-driven immune cell proliferation, differentiation, and survival. Dysregulation of this pathway has been implicated in the pathogenesis of multiple hematologic malignancies, including PTCL and certain B-cell-derived lymphomas, and autoimmune diseases.

Among the JAK family members, JAK1 plays a critical role in transducing signals from a broad range of cytokine receptors involved in lymphocyte activation and survival. In T-cell malignancies such as PTCL, aberrant JAK1-dependent signaling contributes to uncontrolled proliferation and resistance to apoptosis. In addition, dysregulated JAK1-STAT signaling has been implicated in subsets of B-cell lymphomas, where it supports tumor cell survival and cytokine-driven interactions with the tumor microenvironment. Selective inhibition of JAK1 therefore represents a rational therapeutic strategy for targeting cytokine-dependent lymphoid malignancies while potentially avoiding toxicities associated with broader inhibition of JAK2 or JAK3.

In NSCLC without known driver mutations, persistent activation of the JAK/STAT pathway, which is often driven by inflammatory cytokines within the tumor microenvironment, can promote immune evasion by upregulating PD-L1 expression and reinforcing immunosuppressive signaling programs that contribute to T-cell dysfunction and exhaustion. In this context, selective JAK1 inhibition may attenuate these pro–PD-L1 and immune-suppressive signals, thereby modulating the tumor microenvironment and potentially restoring anti-tumor immune activity in patients who have developed resistance to immune checkpoint inhibitors.

Golidocitinib was designed as a highly selective JAK1 inhibitor with the objective of achieving potent suppression of disease-relevant cytokine signaling while maintaining a favorable safety profile. Through selective inhibition of JAK1, golidocitinib blocks downstream STAT activation, thereby reducing tumor cell proliferation and survival in JAK1-dependent malignant lymphoid cells. In NSCLC without known driver mutations, where cytokine-driven JAK/STAT signaling contributes to immune evasion and resistance to immuno-oncology therapies, JAK1 inhibition is also expected to modulate the tumor microenvironment by attenuating immunosuppressive signaling pathways, providing a mechanistic rationale for golidocitinib's evaluation in IO-resistant disease.

In inflammatory skin diseases, JAK1 plays a crucial role in various cytokine pathways involved in the pathogenesis of diseases, such as IL-4, IL-13, TSLP, IL-31, IFN-g, and IL-22. These cytokine pathways are involved in the disruption of the epidermal barrier, the formation of allergic inflammation, the induction of itch, or the immune attack on pigment-producing melanocytes causing white patches.

PTCL

While JAK inhibitors have historically been developed mainly for autoimmune diseases, extensive translational work, including our screening of thousands of cell lines in preclinical studies, highlighted JAK/STAT pathway activation as a key driver in T-cell lymphomas, leading to our deliberate strategy to target PTCL.

Golidocitinib was the **first and only** JAK1 inhibitor approved in China for r/r PTCL as of the Latest Practicable Date, according to CIC. It was also the **first and only** JAK1 inhibitor worldwide receiving both FDA Fast Track and Orphan Drug designations for r/r PTCL as of the same date and according to the same source.

Beyond r/r PTCL, we are evaluating the potential of golidocitinib in combination with chemotherapy for the first-line treatment of PTCL in ongoing IITs in China. In accordance with our communication with the NMPA, the data of IIT trials will be used to support the IND application for JACKPOT28, a planned registrational Phase 3 clinical trial of golidocitinib for the first-line treatment of PTCL.

Market Opportunities and Competitive Landscape

PTCL is a heterogeneous and generally aggressive subset of non-Hodgkin lymphoma ("**NHL**"), accounting for approximately 10% of all NHL cases globally. The incidence of PTCL is higher in China than in Western countries, where PTCL represents approximately 20% of NHL cases.

PTCL arises from mature T cells and is characterized by marked biological and clinical heterogeneity. Most pathological subtypes exhibit aggressive disease behavior and are associated with poor prognosis. First-line treatment typically consists of combination chemotherapy based on the CHOP regimen. In selected patients who achieve an initial response, hematopoietic stem cell transplantation may be used as a consolidation therapy. However, relapse is common, and outcomes for patients with r/r PTCL have historically been poor. Prior to the availability of more recent targeted therapies, treatment options for r/r PTCL were limited and generally associated with modest response rates and short durability, with reported three-year overall survival rates of approximately 21%-28%. As a result, there remains a significant unmet medical need for more effective and durable therapies for patients with PTCL.

According to CIC, the global PTCL drug market grew from US$0.9 billion in 2020 to US$1.5 billion in 2024 at a CAGR of 14.4%. It is projected to further expand to US$6.0 billion in 2035, representing a CAGR of 13.5% from 2024 to 2035. The market size in China increased from US$0.3 billion in 2020 to US$0.5 billion in 2024 at a CAGR of 14.6%, and is expected to reach US$1.7 billion in 2035, reflecting an 12.0% CAGR from 2024 to 2035.

For details, see "Industry Overview — The Oncology Therapeutics Market — The PTCL Market."

Competitive Advantages

Demonstrated clinical efficacy in PTCL

As a first-in-class agent specifically targeting the JAK/STAT signaling pathway in PTCL, golidocitinib represents a novel targeted therapeutic approach for this disease. It is designed to deliver a differentiated "**triple-action**" profile, combining direct anti-tumor activity, anti-inflammatory effects, and immune modulation, with the objective of supporting broad and durable clinical benefit in PTCL.

Registrational trial responses exceed historical benchmarks. In the registrational Phase 2 study of JACKPOT8, golidocitinib demonstrated strong anti-lymphoma activity in r/r PTCL, with an ORR of 44.3% and a complete response ("**CR**") rate of 23.9%. These response rates compare favorably with historical outcomes reported for many prior single-agent targeted therapies in r/r PTCL, where ORRs have often been below 30%. The observed efficacy supports the potential of golidocitinib to meaningfully improve outcomes in this difficult-to-treat patient population.

Tumor response assessed by independent review committee the activity analysis set

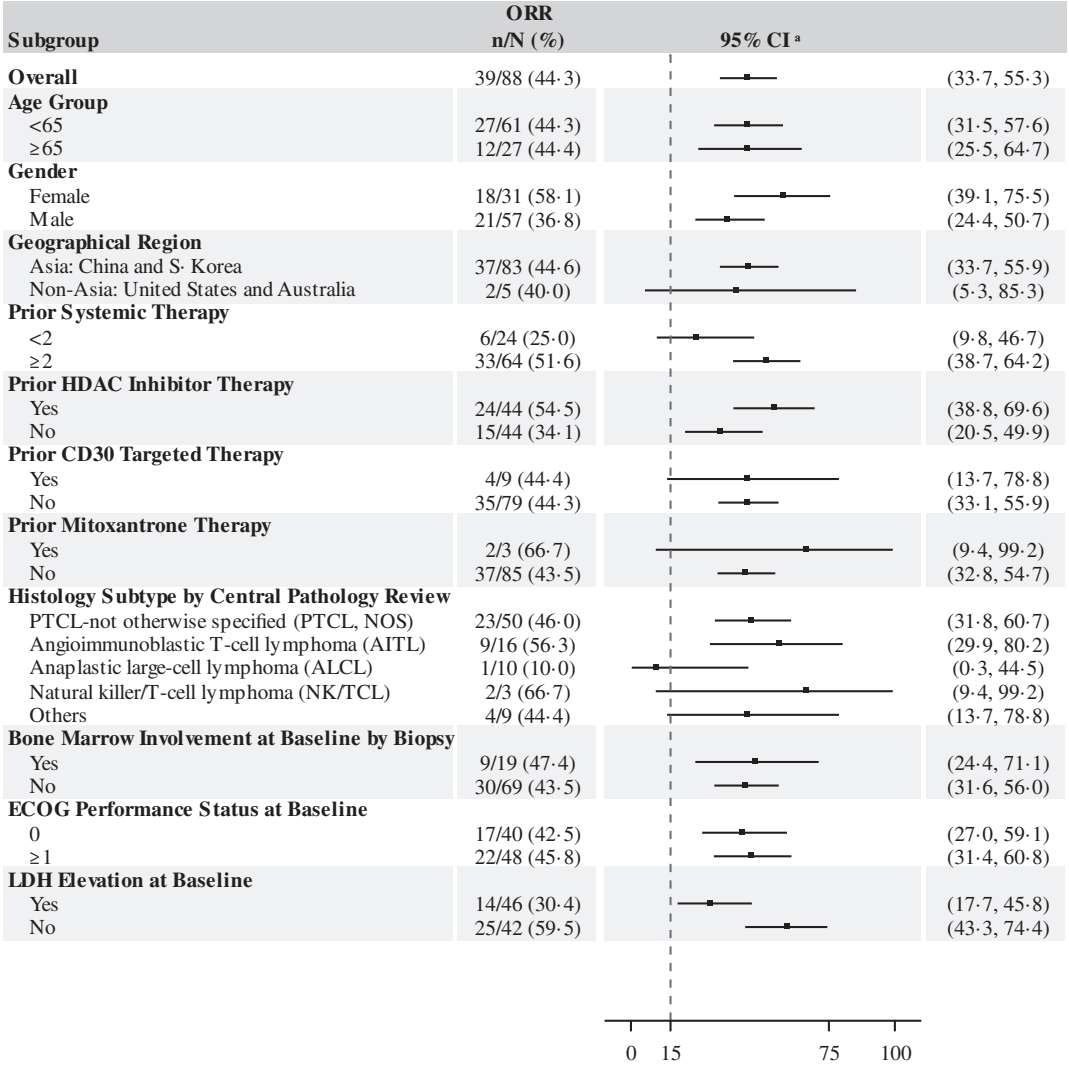
	Patients (n=88)
Best Tumor Response	
Complete Response	21 (24%)
Partial Response	18 (20%)
Stable Disease	17 (19%)
Progressive Disease	20 (23%)
Not Evaluable	12 (14%)
Objective Response Rate (%) (95% CI)	39 (44.3%, 95% CI 33.7-55.3)
Complete Response Rate (%) (95% CI)	21 (23.9%, 95% CI 15.4-34.1)*

*Note: Data are n (%), unless otherwise indicated. *Excluding five patients with radiological complete response who did not have a post-treatment bone marrow biopsy sample available for confirmation, and so were determined to have partial responses.*

Source: Published data of JACKPOT8B on Lancet Oncology 2024

Broad subtype activity with durable survival outcomes. Importantly, as illustrated in the diagram below, golidocitinib demonstrated anti-tumor activity across multiple PTCL subtypes, with ORRs exceeding 40% in several common subtypes. This breadth of activity suggests that golidocitinib may address a major treatment gap in PTCL, where clinical outcomes have historically been poor and heterogeneous across subtypes.

Subgroup analysis of ORR assessed by independent review committee



Note: CI: Confidence Interval; ECOG: Eastern Cooperative Oncology Group; HDAC: Histone Deacetylases; LDH: Lactate Dehydrogenase; PTCL: Peripheral T Cell Lymphoma.

Source: Published data of JACKPOT8B on Lancet Oncology 2024

Beyond initial tumor responses, clinical outcomes were notable for their durability. For instance, in Phase 2 study of JACKPOT8, the median OS was 24.3 months. These results compare favorably with published outcomes for other monotherapy treatments in r/r PTCL and are particularly meaningful given the historically limited survival expectations in this population.

High JAK1 target specificity supporting a favorable safety profile

Preclinical enzymatic studies demonstrate that golidocitinib is a potent and highly selective inhibitor of JAK1. Golidocitinib exhibits more than 200-fold selectivity for JAK1 relative to other members of JAK family in terms of IC_{50} value. This high degree of selectivity is intended to reduce the risk of adverse effects associated with off-target inhibition of other JAK family members.

In JACKPOT8 study, golidocitinib demonstrated a generally manageable safety profile. Grade 3 or 4 drug-related TEAEs were reported in 59% of patients. The most common Grade 3-4 drug-related TEAEs were clinically manageable and generally reversible with appropriate supportive care and dose management.

Favorable PK profile supporting once-daily dosing

Golidocitinib incorporates a distinctive molecular design featuring a "dual hydrogen bond and salt bridge" motif to enhance target engagement. Its physicochemical properties support a relatively long elimination half-life, enabling sustained pathway suppression and convenient dosing.

Clinical PK studies have shown that golidocitinib has a half-life of approximately 45 to 50 hours, supporting once-daily oral administration. Once-daily dosing may improve patient convenience and treatment adherence, particularly in the context of long-term therapy. In addition, golidocitinib exhibits relatively low inter-individual PK variability, which facilitates dose predictability and supports a balanced safety and efficacy profile.

Preclinical studies also indicate that golidocitinib is cleared through multiple metabolic and excretory pathways. It demonstrates minimal inhibitory effects on major drug-metabolizing enzymes and drug transporters, suggesting a low potential for clinically meaningful drug-drug interactions when used in combination with other therapies.

Summary of Clinical Trials and Development Plan

The following table sets forth an overview of the completed, ongoing and planned key clinical trials of golidocitinib for the treatment of PTCL.

Study Name	Indication	Mono/Combo	Treatment Line	Trial Phase	Trial Status	Primary Regions	(Planned) Start Date	Completion Date/ (Planned) Data Readout Date
JACKPOT8	r/r PTCL	Mono	r/r	Registrational Phase 1/2	Completed	Asia Pacific, United States	March 2021	August 2024
JACKPOT19	r/r PTCL	Mono	r/r	Confirmatory Phase 3[1]	Ongoing	Asia Pacific	May 2024	Primary readout in 2H 2027
JACKPOT26	PTCL	Mono	1L	Maintenance Phase 2	Completed	China	March 2022	March 2025
JACKPOT53	PTCL	Combo with CHOP	1L	IIT[2] (Proof-of-concept)	Ongoing	China	August 2024	Primary readout in 1Q 2026
JACKPOT55	PTCL	Combo with CHOP	1L	IIT[2] (Proof-of-concept)	Ongoing	China	March 2025	Primary readout in 1Q 2026
JACKPOT28	PTCL	Combo with CHOP	1L	Registrational Phase 3	Planned	China, United States and Europe	1Q 2026	Primary readout in 2030

Note:

1. *JACKPOT19 is a confirmatory Phase 3 clinical trial to support the full NDA approval of golidocitinib in China for r/r PTCL following the conditional NDA approval of the drug based on its registrational Phase 1/2 trial JACKPOT8 in China.*

2. *The data of JACKPOT53, JACKPOT55 IIT trials and JACKPOT26 Phase 2 trial will be used to support the IND application of JACKPOT28, a planned registrational Phase 3 clinical trial for the first-line treatment of PTCL.*

JACKPOT8

This is a registrational Phase 1/2, open-label, multicenter study to investigate the safety, tolerability, pharmacokinetics, and anti-tumor activity of golidocitinib in patients with PTCL in China, the United States and Australia. Results from this clinical trial supported the conditional NDA approval of golidocitinib in China.

Trial design. This is a multinational, single arm Phase 1/2 clinical study to evaluate the safety, tolerability and anti-tumor efficacy of golidocitinib as monotherapy in patients with r/r PTCL. This study consisted of two parts: Part A (dose escalation and extension cohorts) and Part B (dose expansion cohort). Part B is designed to be initiated after RP2D is defined based on data from Part A.

Trial objectives. The objective of Part A is to assess safety, tolerability, PK and anti-tumor efficacy of golidocitinib. The objective of Part B is to assess anti-tumor efficacy of golidocitinib using IRC assessed ORR as the primary endpoint. The secondary endpoint of Part B included DoR, CRR, and PFS.

Trial status. We initiated this registrational Phase 1/2 trial in March 2021 and completed this trial in August 2024.

Results of Part A study. In the Part A study, a total of 51 patients were enrolled and received golidocitinib treatment at doses of 150 mg or 250 mg once daily. Golidocitinib was tolerated at both doses. The most common Grade 3 or above drug-related TEAEs were neutropenia (27.5%) and thrombocytopenia (11.8%). Based on efficacy and safety, 150 mg once daily was established as the RP2D. Golidocitinib demonstrated a favorable PK profile as an oral agent, and biomarker analysis suggested a potential correlation between JAK/STAT pathway abnormalities and the clinical activity of golidocitinib.

	150 mg (*N* = 35)		**250 mg (*N* = 16)**		**Total (*N* = 51)**	
Common (≥5%) drug-related TEAEs, *n* (%)	**All Grades**	**≥ Grade 3**	**All Grades**	**≥ Grade 3**	**All Grades**	**≥ Grade 3**
Patients with any drug-related TEAEs	26 (74.3)	16 (45.7)	14 (87.5)	8 (50.0)	40 (78.4)	24 (47.1)
Neutropenia[a]	15 (42.9)	11 (31.4)	7 (43.8)	3 (18.8)	22 (43.1)	14 (27.5)
Thrombocytopenia[b]	15 (42.9)	2 (5.7)	8 (50.0)	4 (25.0)	23 (45.1)	6 (11.8)
Transaminases increased[c]	9 (25.7)	3 (8.6)	5 (31.3)	0 (0.0)	14 (27.5)	3 (5.9)
Pneumonia[d]	3 (8.6)	1 (2.9)	6 (37.5)	2 (12.5)	9 (17.6)	3 (5.9)
White blood cell count decreased[e]	7 (20.0)	1 (2.9)	4 (25.0)	1 (6.3)	11 (21.6)	2 (3.9)
Lymphocyte count decreased	5 (14.3)	2 (5.7)	0 (0.0)	0 (0.0)	5 (9.8)	2 (3.9)
Hyperlipidaemia	0 (0.0)	0 (0.0)	1 (6.3)	1 (6.3)	1 (2.0)	1 (2.0)
Staphylococcal sepsis	0 (0.0)	0 (0.0)	1 (6.3)	1 (6.3)	1 (2.0)	1 (2.0)
Drug-induced liver injury	1 (2.9)	0 (0.0)	1 (6.3)	1 (6.3)	2 (3.9)	1 (2.0)

Note: Patients with multiple events within a given preferred term and system organ class were counted only once under the highest CTCAE grade for each preferred term and system organ class, respectively.

CTCAE, Common Terminology Criteria for Adverse Events; TEAE, treatment-emergent adverse event.

a Neutropenia includes neutropenia and neutrophil count decreased.

b Thrombocytopenia includes thrombocytopenia and platelet count decreased.

c Transaminase increased includes aspartate aminotransferase increased, alanine aminotransferase increased, transaminases increased and hepatic enzyme increased.

d Pneumonia includes pneumonia, Pneumocystis jirovecii pneumonia, atypical pneumonia, and pneumonia fungal.

e White blood cell count decreased includes white blood cell count decreased and leukopenia.

Source: Published data of JACKPOT8A on Annals of Oncology 2023

Efficacy results of Part B study. Between February 26, 2021, and October 12, 2022, a total of 104 patients were enrolled and received golidocitinib treatment at 150 mg once daily. Among them, 88 patients were included in the efficacy analysis. As of the data cutoff on August 31, 2023 (with a median follow-up of 13.3 months), the ORR per IRC assessment was 44.3% (95% CI 33.7-55.3), with 21 patients (24%) achieving a complete response and 18 (20%) a partial response.

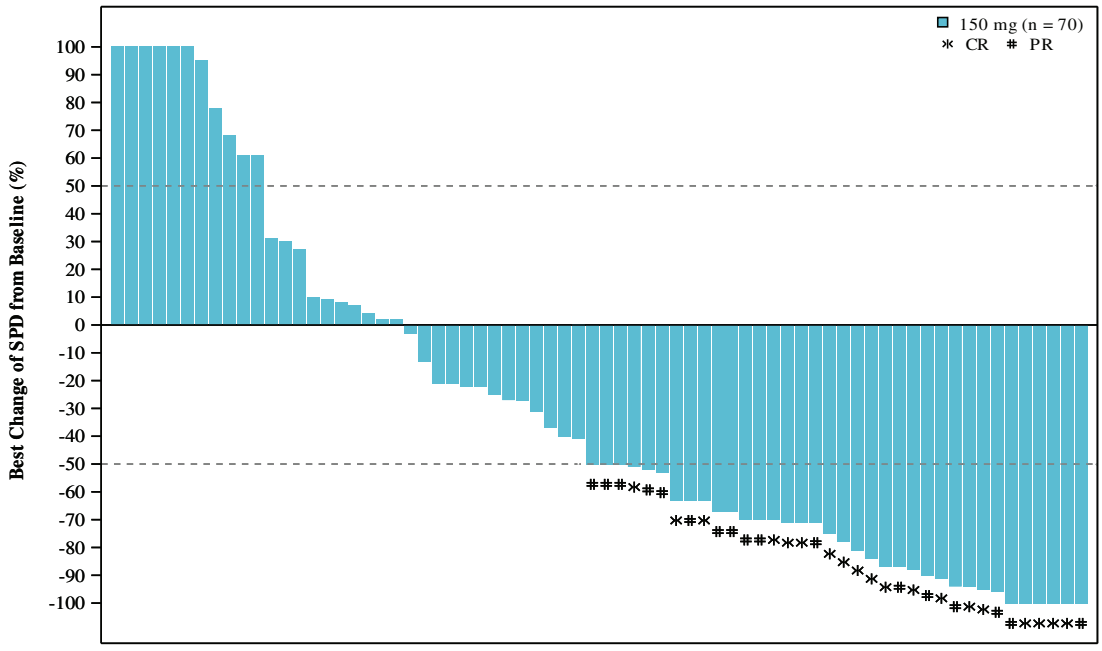
	Patients (n=88)
Best Tumor Response	
Complete Response	21 (24%)
Partial Response	18 (20%)
Stable Disease	17 (19%)
Progressive Disease	20 (23%)
Not Evaluable	12 (14%)
Objective Response Rate (%) (95% CI)	39 (44.3%, 95% CI 33.7-55.3)
Complete Response Rate (%) (95% CI)	21 (23.9%, 95% CI 15.4-34.1)*

*Note: Data are n (%), unless otherwise indicated. *Excluding five patients with radiological complete response who did not have a post-treatment bone marrow biopsy sample available for confirmation, and so were determined to have partial responses.*

Source: Published data of JACKPOT8 on Lance Oncology 2024

The waterfall plot below shows individual patients' best percentage change from baseline in tumor size after treatment.

Waterfall Plot of Best Tumor Size Change after Treatment



Source: Published data of JACKPOT8B at ASH 2023

Safety results of Part B study. In the safety analysis, 61% of patients had grade 3-4 drug-related TEAEs, with the most common being decreased neutrophil count (29%), decreased white blood cell count (26%), decreased lymphocyte count (21%), and decreased platelet count (20%), all of which were clinically manageable and reversible.

JACKPOT26

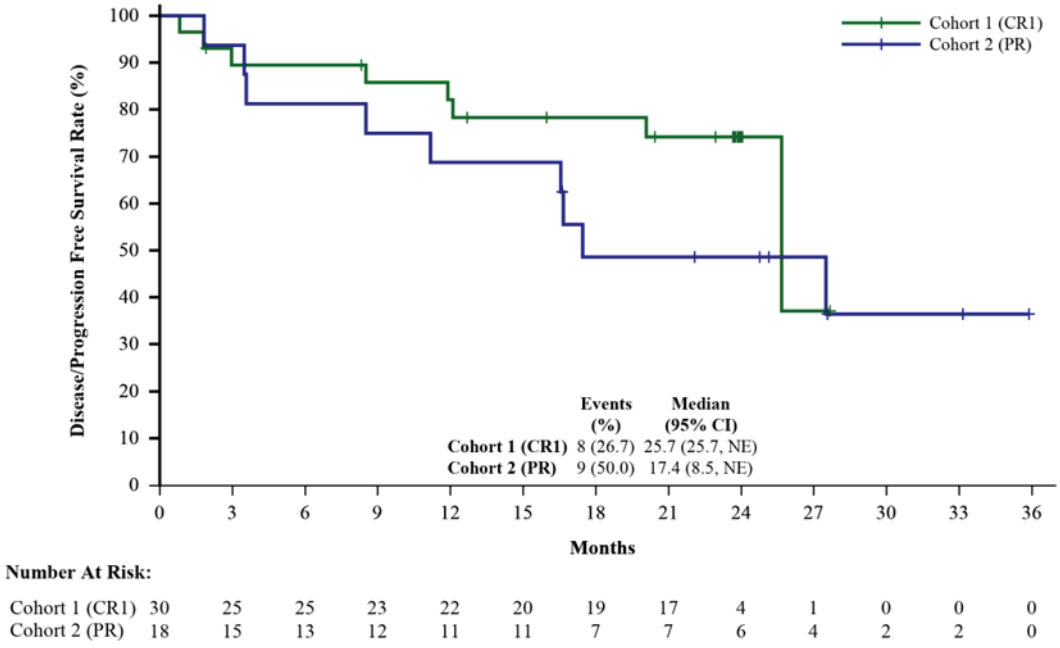
JACKPOT26 is a Phase 2, open-label, multicenter study to investigate the safety and anti-tumor efficacy of golidocitinib in participants with PTCL who have responded after first-line standard therapy.

Trial design. PTCL patients who achieved tumor response post first-line therapy were enrolled and received golidocitinib at 150 mg once daily. This study included two cohorts: cohort 1 (complete response post first-line therapy) and cohort 2 (partial response post first-line therapy). The primary endpoints were AEs and SAEs. The secondary endpoints were DFS rate at one year in cohort 1 and ORR, DoR, PFS rate at one year in cohort 2. Tumor response was assessed by investigators based on CT images per Lugano 2014 criteria.

Trial status. We initiated this trial in March 2022 and completed this trial in September 2025.

Efficacy results. As illustrated in the following plot, in cohort 1, the 12-month and 24-month DFS rates were 82.1% and 74.2%, respectively, indicating a strong long-term outcome for patients. In cohort 2, the median PFS was 17.4 months, with the 12-month and 24-month DoR rates at 71.4% and 47.6%, respectively. The longest PFS recorded was 35.9 months, with the patient still showing a positive response to treatment, suggesting ongoing effectiveness in this cohort.

Kaplan-Meier Plot



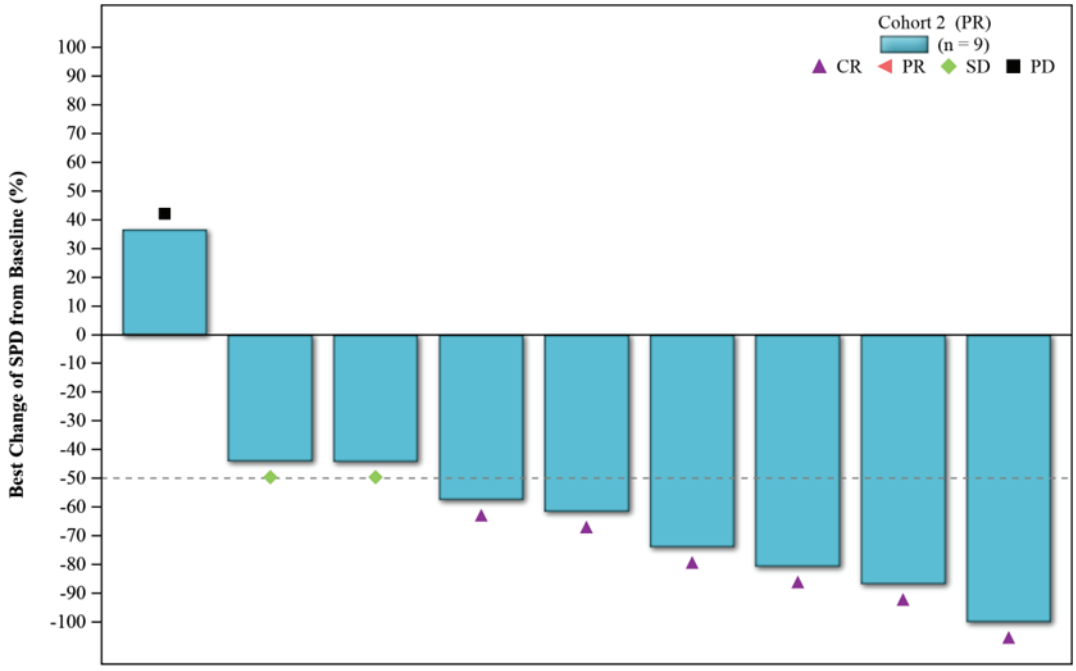
Number At Risk:

Cohort 1 (CR1)	30	25	25	23	22	20	19	17	4	1	0	0	0
Cohort 2 (PR)	18	15	13	12	11	11	7	7	6	4	2	2	0

Source: Oral presentation of JACKPOT26 at ICML 2025

As illustrated in the following plot, in cohort 2, the CRR was 50.0%, demonstrating a significant portion of patients achieving complete tumor response. The median DoR was 23.9 months, further supporting the durability of treatment outcomes. Of the 10 patients with measurable disease at baseline, 9 completed at least one post-treatment tumor assessment. Notably, 80% of patients experienced tumor shrinkage of target lesions, and 60% achieved a complete tumor response, highlighting the efficacy of the treatment in reducing tumor burden.

Waterfall Plot of Best Change in SPD in Cohort 2



Source: Oral presentation of JACKPOT26 at ICML 2025

Safety results. The most common (≥2 patients) ≥ grade 3 drug-related TEAEs were hematological adverse events in nature, which were similar to TEAEs previously reported for golidocitinib. The majority of TEAEs were reversible and clinically manageable. 16.7% of the patients had dose reduction due to drug-related TEAEs. 10.4% of the patients discontinued treatment due to drug-related TEAEs. No drug-related TEAEs with fatal outcome.

JACKPOT19

This is a Phase 3, open-label, randomized, multinational study to investigate the anti-tumor efficacy of golidocitinib versus investigator's choice in adult patients with r/r PTCL. This trial is a confirmatory Phase 3 clinical trial to support the full NDA approval of golidocitinib in China for r/r PTCL following the conditional NDA approval based on its registrational Phase 1/2 trial JACKPOT8 in China.

Trial design. This is a Phase 3, open-label, randomized, multinational study to evaluate the anti-tumor efficacy of golidocitinib versus investigator's choice in adult patients with r/r PTCL. Participants will be randomly assigned to Arm 1 (golidocitinib) or Arm 2 (investigator's choice) in a ratio of 1:1. The stratification factors include baseline international prognostic index, region, and histological subtype by local testing.

Trial objectives. The primary endpoint of this trial is PFS assessed by IRC. Secondary endpoints include OS, ORR, CRR and DoR.

Trial status. We initiated this registrational Phase 3 trial in May 2024 and expect to obtain primary data readout in the second half of 2027.

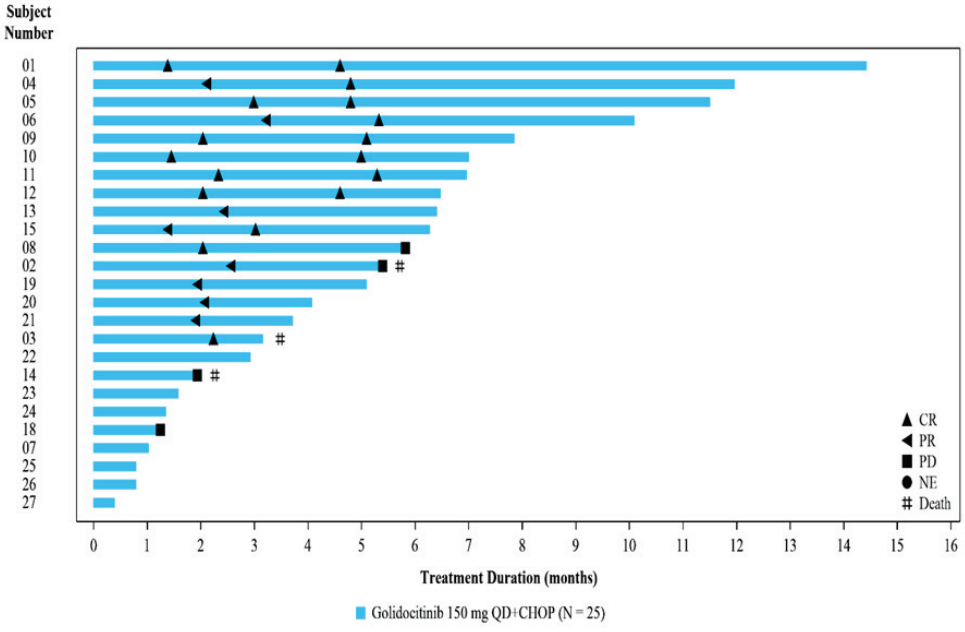
JACKPOT53 and JACKPOT55

JACKPOT53 and JACKPOT55 are investigator-initiated trials of golidocitinib in combination with CHOP ("**Go-CHOP**") in patients with newly diagnosed PTCL. These two studies applied different regimens of golidocitinib. The data of JACKPOT53 and JACKPOT55 as well as Phase 2 trial JACKPOT26 will be used to support an IND application of JACKPOT28, a planned registrational Phase 3 clinical trial for the first-line treatment of PTCL. These two studies were initiated by a leading public hospital in Beijing and another public hospital in Guangzhou, respectively.

JACKPOT53 is an ongoing Phase 1/2, single-center, single-arm clinical trial. JACKPOT53 was initiated in August 2024 and is expected to obtain primary readout in the first quarter of 2026.

In JACKPOT53, Go-CHOP regimen (150 mg of golidocitinib once daily + CHOP) demonstrated encouraging anti-tumor activity and tolerable safety profile. The reported ORR was 88.9% and CR rate was 61.1% in newly diagnosed patients with PTCL.

Swimmer Plot of JACKPOT53



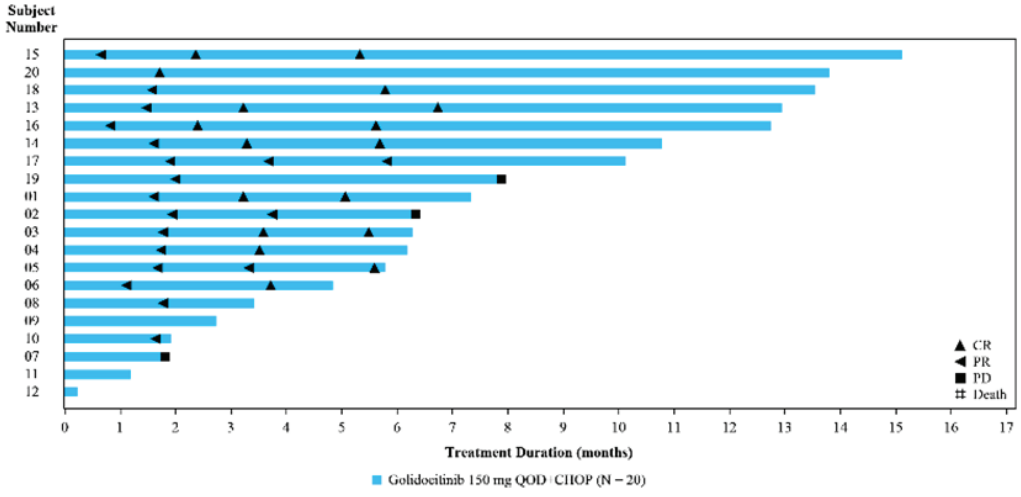
Source: Published data of JACKPOT53 at ASH 2025

JACKPOT55 was initiated in March 2025 and is expected to obtain primary readout in the first quarter of 2026.

In JACKPOT55, Go-CHOP regimen (150 mg of golidocitinib every other day + CHOP) demonstrated strong early anti-tumor activity in patients with newly diagnosed PTCL. The reported ORR was 94.1% and CR rate was 64.7%. In addition, 85% of patients remained on treatment, with the longest PFS exceeding 15 months, and the safety profile was described as manageable with no treatment discontinuations due to TRAEs.

The swimmer plot below shows the treatment duration for individual patients covered in JACKPOT55.

Swimmer Plot of JACKPOT55



Note: CHOP: combined chemotherapy with cyclophosphamide, doxorubicin, vincristine and prednisone; CR: Complete Response; N: Number of participants in the analysis set; NE: Not Evaluable; PD: Progressive Disease; PR: Partial Response; QD: Quaque Die (once daily); SD: Stable Disease.

Source: Presentation at J.P. Morgan Healthcare Conference 2026

JACKPOT28

JACKPOT28 is a registrational Phase 3, randomized, double-blind, multicenter study of golidocitinib in combination with chemotherapy followed by golidocitinib monotherapy as a maintenance therapy in patients with newly diagnosed PTCL. We plan to submit IND and initiate this trial in the first quarter of 2026.

NSCLC without known driver mutations

In NSCLC without known driver mutations, aberrant activation of JAK/STAT pathway, often driven by inflammatory cytokines within the tumor microenvironment, may facilitate immune evasion by upregulating PD-L1 expression and reinforcing immunosuppressive signaling programs that contribute to progressive T-cell dysfunction and exhaustion. Accordingly, JAK1 inhibition with golidocitinib may attenuate these pro-PD-L1 and immune-suppressive signals, thereby modulating the tumor microenvironment and potentially restoring anti-tumor immune activity.

Consistent with this rationale, preclinical data indicate that JAK inhibition can rescue exhausted T-cell function and enhance sensitivity to checkpoint blockade, providing a mechanistic basis for combining golidocitinib with anti-PD-1/PD-L1 therapies.

We are exploring golidocitinib's potential in combination with an anti-PD(L)-1 antibody in NSCLC without known driver mutations in an ongoing investigator-initiated trial in China, JACKPOT33. The data of JACKPOT33 study will be used to support the IND application of JACKPOT66, a planned registrational Phase 3 clinical trial for NSCLC without known driver mutations.

Market Opportunities and Competitive Landscape

NSCLC without known driver mutations represents a major unmet need because many patients must rely on immunotherapy-based regimens, yet an anti-PD(L)-1 antibody monotherapy delivers only modest disease control for a large proportion of patients, especially those with intermediate PD-L1 expression. In the first-line PD-L1 monotherapy population, median PFS was only 5.4 months, illustrating how quickly many tumors progress despite treatment.

A key biological reason is that these tumors often exist in an immune-suppressed microenvironment where T cells become chronically stimulated and exhausted, losing effective anti-tumor function and contributing to primary or early resistance to checkpoint blockade, thereby creating a clear need for new approaches that can re-energize anti-tumor immunity and improve the depth and durability of benefit beyond what PD-1 monotherapy achieves today.

The global NSCLC without known driver mutations market grew from US$13.3 billion in 2020 to US$21.9 billion in 2024 at a CAGR of 13.3%. It is projected to further expand to US$41.8 billion in 2035, representing a CAGR of 6.0% from 2024 to 2035. As of the Latest Practicable Date, there had not been small-molecule targeted therapy approved for NSCLC without known driver mutations globally.

For details, see "Industry Overview — The Oncology Therapeutics Market — The NSCLC Without Known Driver Mutations Market."

Summary of Clinical Development

The following table sets forth an overview of the ongoing and planned clinical trials of golidocitinib for the treatment of NSCLC without known driver mutations.

Study Name	Indication	Mono/Combo	Line of Treatment	Trial Phase	Trial Status	Region	(Planned) Start Date	(Planned) Data Readout Date
JACKPOT33	NSCLC	Combo with anti-PD (L)-1 Antibody	1L	IIT[1] (Proof-of-concept)	Ongoing	China	March 2024	Primary readout in 3Q 2026
JACKPOT66	NSCLC	Combo with IO	1L	Registrational Phase 3	Planned	China	2H 2026	Primary readout in 2H 2028

Note:

1. *The data of JACKPOT33 will be used to support the IND application of JACKPOT66, a planned registrational Phase 3 clinical trial for NSCLC without known driver mutations.*

JACKPOT33

This is an open-label, single-arm investigator-initiated trial to assess the safety and efficacy of golidocitinib combined with an anti-PD(L)-1 antibody in PD-L1-positive, treatment-naive, locally advanced or metastatic NSCLC.

Trial status. This IIT trial was initiated in March 2024. Primary readout for this IIT is expected to be obtained in the third quarter of 2026.

JACKPOT66

JACKPOT66 is a planned Phase 3, randomized, open-label, multi-center study of golidocitinib combined with immunotherapy for the first-line treatment of patients with locally advanced or metastatic NSCLC without known driver mutations. We plan to submit the IND to the NMPA in the third quarter of 2026 and initiate this trial in the second half of 2026 following IND approval.

Primary ITP

We are developing golidocitinib for the treatment of primary ITP. Golidocitinib is a selective JAK1 inhibitor that reduces overactive JAK/STAT cytokine signaling, which can drive immune-mediated platelet destruction and impaired platelet production. By selectively targeting JAK1, it is designed to deliver immunomodulatory benefit while limiting broader JAK inhibition that may be associated with more off-target side effects.

In ITP, many patients have an abnormally pro-inflammatory cytokine environment, reflecting immune dysregulation that supports autoreactive T- and B-cell responses and continued platelet clearance. By inhibiting JAK1, golidocitinib can dampen downstream STAT activation triggered by multiple cytokines, thus may reduce harmful immune activity, decrease platelet destruction, and help restore megakaryocyte function and platelet production over time.

We are assessing golidocitinib in an ongoing Phase 2 clinical trial, JACKPOT16, for r/r primary ITP in China.

Market Opportunities and Competitive Landscape

Primary ITP is an acquired autoimmune bleeding disorder characterized by immune-mediated platelet destruction and impaired platelet production. Patients typically present with platelet counts below 100×10^9/L, increased bleeding risk and, in some cases, thrombotic complications, resulting in a meaningful reduction in quality of life. Because ITP is often chronic and unpredictable, many patients require long-term diseases control strategies that do not impose excessive treatment burden.

A key unmet need in ITP is the limited durability of response achieved with first-line therapies. Corticosteroids and intravenous immunoglobulin ("**IVIG**") are effective in rapidly increasing platelet counts, but a substantial proportion of adult patients relapse after steroids are tapered or discontinued. Long-term steroid use is also associated with significant toxicity, including increased infection risks and osteoporosis, particularly in patients requiring repeated treatment courses.

For r/r ITP, available second-line therapies can raise platelet counts but have important limitations. Thrombopoietin-based therapies, including recombinant human thrombopoietin ("**rhTPO**") and thrombopoietin receptor agonists ("**TPO-RAs**"), often require continuous administration to maintain platelet level needed, with platelet counts declining after discontinuation in some patients. Long-term use raises concerns regarding cumulative toxicity, and high treatment costs may limit real-world access and adherence. Other treatment options also leave unmet needs.

Overall, there remains a need for therapies that can deliver sustained platelet responses, reduce reliance on steroids and offer a safer, more practical long-term treatment option for patients with r/r ITP.

The global ITP drug market grew from US$2.0 billion in 2020 to US$2.6 billion in 2024 at a CAGR of 7.4%. It is projected to further expand to US$6.8 billion in 2035, representing a CAGR of 9.1% from 2024 to 2035. The market size in China increased from US$0.2 billion in 2020 to US$0.3 billion in 2024 at a CAGR of 10.9%, and is expected to reach US$1.1 billion in 2035, reflecting a 11.2% CAGR from 2024 to 2035.

As of the Latest Practicable date, there was one BTK inhibitor approved for ITP globally.

For details, see "Industry Overview — The Oncology Therapeutics Market — The NSCLC Without Known Driver Mutations Market."

Competitive Advantages

Novel mechanism of action. No JAK inhibitor is approved in ITP as of the Latest Practicable Date. As a first-in-class agent specifically targeting the JAK/STAT signaling pathway in PTCL, golidocitinib represents a novel targeted therapeutic approach for this disease.

Highly selective JAK1 inhibitor offering favorable safety profile. Golidocitinib exhibits more than 200-fold selectivity for JAK1 relative to other members of JAK family in terms of IC_{50} value. This high degree of selectivity is intended to reduce the risk of adverse effects associated with off-target inhibition of other JAK family members.

Favorable PK profile supporting once-daily dosing. Golidocitinib incorporates a distinctive molecular design featuring a "dual hydrogen bond and salt bridge" motif to enhance target engagement. Its physicochemical properties support a relatively long elimination half-life, enabling sustained pathway suppression and convenient dosing.

Summary of Clinical Trials

The following table sets forth an overview of the ongoing clinical trial of golidocitinib for primary ITP.

Study Name	Indication	Mono/Combo	Line of Treatment	Trial Phase	Trial Status	Region	Start Date	(Planned) Completion Date/Data Readout Date
JACKPOT16 . . .	Primary ITP	Mono	r/r	2	Ongoing	China	December 2025	Primary readout in 1H 2028

JACKPOT16

Trial design. JACKPOT16 is a multicenter clinical study to evaluate the safety and efficacy of golidocitinib in patients with r/r primary ITP. The study consists of two parts: Part A dose escalation and Part B dose expansion. Part A is designed to obtain the safety profile of golidocitinib in patients with ITP and the recommended dose for the randomized cohort in Part B. Part B is a randomized, double-blind, placebo-controlled study, and the primary objective of this part is to evaluate the preliminary efficacy of golidocitinib in patients with ITP.

Trial objectives. The primary objective of Part A of JACKPOT16 is to assess the safety and tolerability of golidocitinib. The primary objective of Part B of JACKPOT16 is to assess the efficacy for r/r primary ITP versus placebo, with the proportion of patients with a platelet count $\geq 50 \times 10^9$/L on at least four of six scheduled visits between weeks 14 and 24 as primary endpoint.

Trial status and plan. We initiated this trial in December 2025 and expect to obtain primary readout in the first half of 2028.

Dermatology indications

In addition to oral capsule, we are developing golidocitinib ointment for dermatology indications. Golidocitinib ointment is currently under GMP production and GLP toxicology study. We plan to initiate a Phase 1/2 proof-of-concept trial of golidocitinib ointment for mild-to-moderate atopical dermatitis ("**AD**") in 2027.

Oral golidocitinib has shown rapid and effective antipruritic (anti-itch) efficacy in clinical practice. However, topical administration of JAK inhibitors offers advantages over oral administration for mild-to-moderate skin inflammation disease as it can minimize the systemic exposure to avoid serious systemic adverse effects associated with oral administration. A topical drug needs to effectively penetrate the skin and remain in the dermis at a sufficient concentration for sustained duration. As of the Latest Practicable Date, only 1.5% ruxolitinib cream was approved for use in the United States, and 0.5% delgocitinib ointment was approved in Japan. Owing to its unique molecular design, golidocitinib possesses excellent skin penetration and is able to remain in the skin for long periods with high concentration. Therefore, golidocitinib ointment may achieve rapid relief of inflammation while avoiding the systemic side effects.

Birelentinib — An Innovative Lyn/BTK Dual Inhibitor

Overview

Birelentinib (DZD8586) is an innovative dual inhibitor of lymphocyte-specific protein tyrosine kinase ("**Lyn**") and Bruton's tyrosine kinase ("**BTK**"). Although currently available BTK inhibitors have delivered meaningful clinical benefit in certain B-cell non-Hodgkin lymphoma ("**B-NHL**") subtypes, the development of treatment resistance remains a major clinical challenge. Resistance is primarily driven by two mechanisms: (i) mutations at the C481 binding site of BTK (collectively referred to as C481X mutations), and (ii) reactivation of BCR signaling through alternative pathways that no longer depend on BTK. As of the Latest Practicable Date, no approved drug was able to overcome both resistance mechanisms simultaneously, according to CIC.

Birelentinib is different. It is designed to simultaneously inhibit both BTK-dependent and BTK-independent B-cell receptor ("**BCR**") signaling pathways, with the objective of overcoming key limitations associated with single-target BTK inhibitors. Through this dual-pathway mechanism, birelentinib is intended to suppress oncogenic BCR signaling and inhibit tumor growth across multiple subtypes of B-NHL. As of the Latest Practicable Date, it was the **first and only** dual Lyn/BTK inhibitor in clinical development, according to CIC.

Birelentinib received Fast Track Designation from the U.S. FDA in August 2025 for the treatment of r/r CLL/SLL. A pooled analysis from two clinical studies in heavily pretreated patients with CLL/SLL was selected for oral presentation at both the 2025 American Society of Clinical Oncology ("**ASCO**") meeting and the 18th International Conference on Malignant Lymphoma ("**ICML**"). Based on these data, we initiated an international multi-center Phase 3 clinical trial of birelentinib for r/r CLL/SLL in September 2025.

Beyond CLL/SLL, we are exploring birelentinib's potential in DLBCL. So far, BTK inhibitors have only shown limited clinical efficacy in non-GCB subtype of DLBCL. We hypothesize that incomplete blockade of BCR signaling is the likely reason. By simultaneously inhibiting both BTK and Lyn signaling, birelentinib may overcome these limitations and improve treatment outcomes in r/r DLBCL. This hypothesis was supported by the results from a Phase 2 clinical study evaluating birelentinib monotherapy in r/r DLBCL, TAI-SHAN9, which was presented at the 2025 European Hematology Association ("**EHA**") Congress and the 18th ICML. Significant anti-tumor activities were observed in both GCB and non-GCB DLBCL subtypes.

We are also developing birelentinib beyond relapsed/refractory settings in combination with BCL2 inhibitor and chemotherapy for the first-line treatment of CLL/SLL and DLBCL, respectively. Moreover, we are evaluating birelentinib's potential in immunology indication in an ongoing Phase 2 clinical trial for r/r primary immune thrombocytopenia ("**ITP**") in China.

Drug Design and Mechanism of Action

Birelentinib is an innovative, non-covalent dual inhibitor of Lyn and BTK designed to selectively target key signaling nodes within the BCR pathway while maintaining selectivity against other members of the TEC kinase family. In B cells, Lyn is one of the first kinases activated following BCR engagement. BTK functions downstream of Lyn in the BCR signaling cascade and is essential for amplifying and propagating activation signals.

By inhibiting both BTK and Lyn, birelentinib is intended to suppress not only canonical BTK-dependent BCR signaling, but also BTK-independent "escape" pathways that can emerge following BTK only inhibition. This dual-pathway coverage is particularly relevant in clinical settings where relapse is driven by classic BTK binding-site mutations, such as C481X mutations, as well as alternative resistance mechanisms that reactivate BCR signaling through parallel or compensatory nodes. Through this mechanism, birelentinib has demonstrated the ability to inhibit tumor growth across multiple B-NHL subtypes, including CLL, SLL and DLBCL.

Furthermore, the dual-pathway coverage is beneficial to address immune-mediated diseases such as ITP, where pathogenic autoantibody production by B cells and Fc receptor-mediated platelet destruction by macrophages are driven by BTK- and Lyn-dependent signaling cascades. By targeting both kinases, birelentinib is designed to modulate upstream autoimmune drivers and downstream effector mechanisms of platelet destruction, providing a mechanistic rationale for its evaluation in ITP.

CLL/SLL

Birelentinib received Fast Track Designation from the U.S. FDA in August 2025 for the treatment of r/r CLL/SLL. We initiated TAI-SHAN6, an international multi-center Phase 3 clinical trial of birelentinib for r/r CLL/SLL, in September 2025.

Beyond the relapsed or refractory setting, we are developing birelentinib as part of combination therapy aimed at achieving deeper response in CLL/SLL. Deeper responses may enable time-limited treatment approaches, in which patients receive therapy for a defined duration rather than continuous, indefinite treatment. Such approaches have the potential to maintain disease control while reducing long-term treatment burden, cumulative toxicity and the practical impact of prolonged therapy.

To evaluate this approach, we are conducting TAI-SHAN10, an ongoing Phase 2 clinical trial in China investigating birelentinib in combination with a BCL2 inhibitor as first-line treatment for CLL/SLL.

Market Opportunities and Competitive Landscape

CLL/SLL is a malignancy of mature B cells characterized by lymphocytosis, lymphadenopathy, hepatosplenomegaly and, in advanced stages, bone marrow failure leading to cytopenia. In current clinical practice, BTK inhibitors are widely used as first-line therapy for CLL/SLL patients, as recommended by major treatment guidelines. Other therapeutic options include BCL2 inhibitors, PI3K inhibitors and chemotherapies.

Despite advances in targeted therapy, all patients eventually relapse or develop refractory disease over time. Treatment options become increasingly limited after failure of targeted agents. In some regions, including China, access to certain therapies such as BCL2 inhibitors or PI3K inhibitors may be restricted by regulatory approval or reimbursement considerations. As a result, clinicians may need to rely on CD20 antibody monotherapy or chemotherapy in the post-BTK inhibitor setting, where real-world overall response rates have been reported at approximately 25%-36%.

In addition, there remains an unmet need for safer and more tolerable treatment options for vulnerable patient populations. Patients with del (17p) or TP53 mutations generally respond poorly to chemotherapy, while older patients and those with significant comorbidities may be unable to tolerate intensive regimens. For these patients, the unmet need encompasses both efficacy and tolerability, highlighting the importance of therapies that can deliver meaningful disease control with improved safety profiles.

According to CIC, the global CLL/SLL drug market grew from US$8.5 billion in 2020 to US$13.2 billion in 2024 at a CAGR of 11.7%. It is projected to further expand to US$41.3 billion in 2035, representing a CAGR of 10.9% from 2024 to 2035. China remains a key growth engine, with market size increasing from US$0.5 billion in 2020 to US$0.7 billion in 2024 at a CAGR of 9.8%, and is expected to reach US$2.6 billion in 2035, reflecting an 12.1% CAGR from 2024 to 2035.

As of the Latest Practicable date, there were five BTK inhibitor approved for CLL/SLL globally.

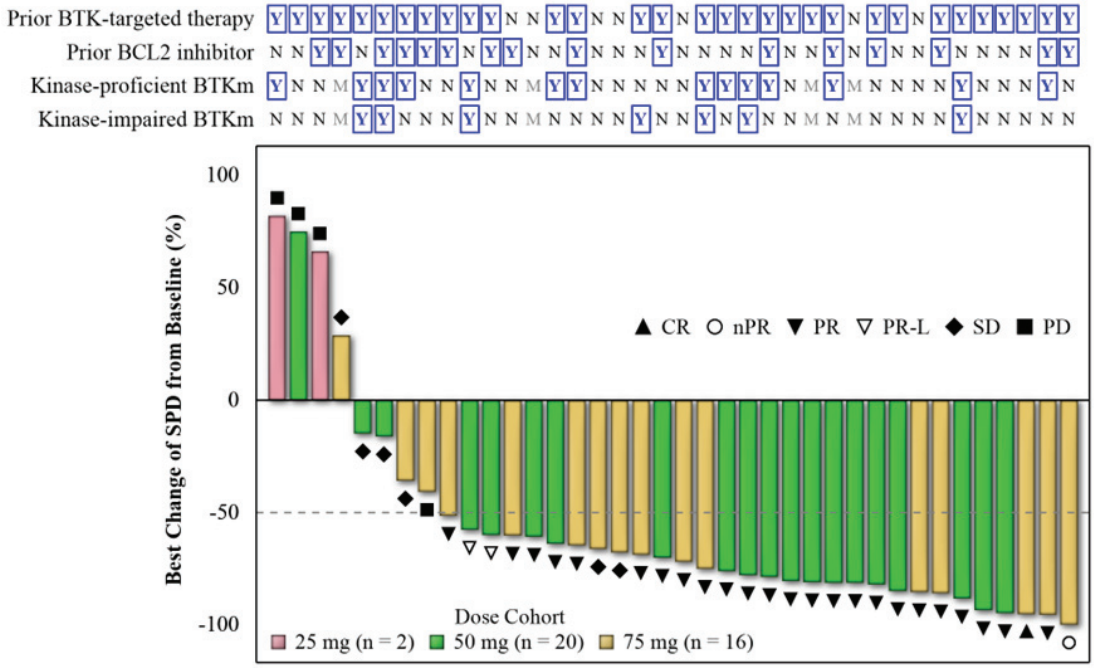
For details, see "Industry Overview — The Oncology Therapeutics Market — The CLL/SLL Market."

Competitive Advantages

Compelling efficacy signals in heavily pretreated r/r CLL/SLL patients

High response rate in pretreated r/r CLL/SLL. The results of a pooled analysis from two clinical studies, Phase 1 (TAI-SHAN5) and Phase 2 (TAI-SHAN8), were selected as oral presentations at both 2025 American Society of Clinical Oncology ("**ASCO**") meeting and the 18th International Conference on Malignant Lymphoma ("**ICML**"). As of December 2025, patients treated with birelentinib at 50 mg achieved an ORR of 85%.

Waterfall Plot of Best Change in Tumor Burden From Baseline in r/r CLL/SLL



Note: CRi: Complete Response with Incomplete Marrow Recovery; M: Missing; N: No; PR: Partial Response; PR-L: Partial Response with Lymphocytosis; SD: Stable Disease; PD: Progressive Disease; SPD: Sum of the Product of the Perpendicular Diameters. Y: Yes. A total of 35 patients with both baseline and at least one post-treatment tumor assessment were included in the efficacy analysis set, and among them, 34 patients with baseline measurable disease were shown in the figure. Objective response included CRi, PR and PR-L.

Source: Presentation at J.P. Morgan Healthcare Conference 2026

Broad activity in resistant and high-risk subgroups. Clinical responses were observed across challenging subgroups, including patients previously treated with covalent or non-covalent BTK inhibitors, BTK degraders, and BCL2 inhibitors, as well as those carrying classic BTK resistance mutations and other BTK alterations (including kinase-impaired mutations). For instance, as of the December 2025 for TAI-SHAN8, responses were observed in patients with prior BTK-targeted therapies, including covalent BTKi (81%, 13/16), non-covalent BTKi (100%, 2/2), and BTK degrader (50%, 1/2).

Encouraging durability and FDA Fast Track Recognition. Durability of response was also encouraging, with an estimated 9-month DoR rate of 80% from the pooled analysis of TAI-SHAN5 and TAI-SHAN8. As a recognition of its therapeutic potential, the U.S. FDA granted birelentinib Fast Track Designation in August 2025 for r/r CLL/SLL after at least two prior lines of therapy, including a BTK inhibitor and a BCL2 inhibitor.

Differentiated safety profile supporting long-term use and combinations

Across clinical trials, birelentinib has demonstrated a generally manageable safety profile. There were no reported instances of drug-related bleeding, atrial fibrillation, or other major cardiac events, which is notable given class-wide safety considerations associated with chronic BTK inhibition.

This safety and tolerability profile is particularly important given the intended role of birelentinib not only as a monotherapy, but also as a potential backbone for combination regimens, which often require sustained dosing to achieve durable benefit. We are assessing birelentinib's potential as part of a combination therapy in the first-line setting for CLL/SLL in an ongoing Phase 2 clinical trial, TAI-SHAN10, as described below.

Summary of Clinical Trials and Development Plan

The following table sets forth an overview of key ongoing and planned clinical trials of birelentinib for the treatment of CLL/SLL.

Study Name	Indication	Mono/Combo	Line of Treatment	Trial Phase	Trial Status	Primary Regions	(Planned) Start Date	(Planned) Data Readout Date
TAI-SHAN8	r/r CLL/SLL	Mono	2L/2L+	Phase 2	Ongoing	China	April 2024	Primary readout in 1Q 2026
TAI-SHAN6	r/r CLL/SLL	Mono	2L/2L+	Registrational Phase 3	Ongoing	China, Europe	September 2025	Interim data readout in 2H 2027
TAI-SHAN10	CLL/SLL	Combo with BCL2 inhibitor	1L	Phase 2	Ongoing	China	October 2025	Primary readout in 3Q 2026
TAI-SHAN16	CLL/SLL	Combo with BCL2 inhibitor	1L	Registrational Phase 3	Planned	China	1H 2027	Primary readout in 2031

TAI-SHAN8

This is a Phase 2, open-label, multicenter study to evaluate the anti-tumor efficacy, safety, tolerability, and pharmacokinetic characteristics of birelentinib in patients with r/r CLL/SLL.

Trial design. The study is divided into two parts: A and B. Relapsed or refractory CLL/SLL patients, including those intolerant to current therapy, are enrolled into the study. Participants are first randomized to cohort 1 or cohort 2, and cohort 3 is determined based on safety and efficacy data from both cohorts and after SRC assessment. Dose of birelentinib ranged from 25 to 75 mg. Based on the safety and efficacy data from cohorts 1, 2, 3, the dose expansion cohort will further enroll patients who receive selected dose levels. Part A data will be combined to determine the recommended Phase 3 dose ("**RP3D**").

Trial objectives. Primary endpoint of this trial is investigator assessed ORR. Secondary endpoints of this trial include investigator assessed PFS, DoR, TTR, safety, and PK.

Efficacy results as of December 2025. As of December 2025, a total of 64 patients with r/r CLL/SLL had been enrolled and received birelentinib at doses ranging from 25 mg to 100 mg once daily. The median number of prior therapies was 2 (range 1-8). Del(17p) and/or TP53 mutation was detected in 40% of the patients. Prior therapies included BTK-targeted therapies (81%, including 77% treated with covalent BTK inhibitor, 9% treated with non-covalent BTK inhibitor and 8% treated with BTK degrader), BCL2 inhibitor (38%), and chemoimmunotherapy (55%). Kinase proficient BTK mutation was detected in 43% of the patients and kinase impaired BTK mutation was detected in 21% of the patients.

The recommended phase 3 dose was determined as 50 mg once daily ("**QD**"). At this dose level, the ORR was 85%. Tumor response observed in patients with prior BTK-targeted therapies, including covalent BTKi (81%, 13/16), non-covalent BTKi (100%, 2/2), and BTK degrader (50%, 1/2). In patients with prior exposure to both BTK-targeted therapy and BCL2 inhibitor, the ORR was 83% (5/6). Tumor response observed in patients with kinase-proficient mutations (78%, 7/9) and kinase-impaired mutations (60%, 3/5).

With prolonged follow-up, sustained anti-tumor efficacy was observed. At 50 mg cohort, median duration of follow-up was longer than 11 months. Median PFS has not been reached, with 60% of the patients still event-free.

Safety results as of October 2025. Birelentinib showed favorable safety profile at 50 mg once daily ("**RP3D**"), and no new safety signals were identified. The most common treatment-related TEAEs of all grades included neutropenia and thrombocytopenia. No atrial fibrillation, or drug-related major bleeding was reported. TEAE leading to treatment discontinuation in 1 patient (2%). No treatment-related TEAE leading to death was reported.

Trial status. We initiated this Phase 2 trial in April 2024 and expect to obtain primary readout of this trial in the first quarter of 2026.

TAI-SHAN6

This is a registrational Phase 3, open-label, randomized, global multicenter study to evaluate the anti-tumor efficacy of birelentinib versus investigator's choice in patients with r/r CLL or SLL. We initiated TAI-SHAN6 following the determination of RP3D, and regulatory communications with China CDE and EMA regarding the clinical trial design of TAI-SHAN6 as a registrational trial.

Trial design. The target population of this study is patients diagnosed with r/r CLL/SLL, who have failed at least one prior BTK inhibitor treatment, as assessed by the investigator. Patient who meets inclusion criteria and does not meet exclusion criteria will be randomized to arm 1 (birelentinib) or arm 2 (investigator's choice) in a 1:1 ratio.

Trial objectives. The primary endpoint for this trial is IRC assessed PFS and the secondary endpoints include investigator assessed ORR, PFS, DoR, IRC assessed ORR, DoR, OS, safety, and PK.

Trial status. We initiated this registrational Phase 3 trial in September 2025 and expect to complete interim analysis for this trial in the second half of 2027.

TAI-SHAN10

This is a Phase 2 study to investigate the efficacy and safety of birelentinib in combination with a BCL2 inhibitor in participants with CLL/SLL who have not received any systemic therapy. This study consists of two parts: Part A is the safety lead-in phase, and Part B is the dose expansion phase.

Trial objectives. The primary endpoints for this trial are incidences of AEs (Part A) and 2-year PFS rate assessed by investigator (Part B). The secondary endpoints include investigator assessed PFS and ORR.

Trial status. We initiated this Phase 2 trial in October 2025 and expect to obtain preliminary data readout in the third quarter of 2026.

TAI-SHAN16

TAI-SHAN16 is a planned Phase 3, randomized, open-label, multi-center study of birelentinib combined with a BCL2 inhibitor as first-line treatment in patients with CLL/SLL for defined treatment duration. We plan to communicate with CDE regarding the design of this trial in the third quarter of 2026 and initiate this trial in the first half of 2027 following the IND approval.

DLBCL

Beyond CLL/SLL, we are exploring birelentinib's potential in DLBCL. So far, BTK inhibitors have only shown limited clinical efficacy in non-GCB subtype of DLBCL. We hypothesize that incomplete blockade of BCR signaling is the likely reason. By simultaneously inhibiting both BTK and Lyn signaling, birelentinib may overcome these limitations and improve treatment outcomes in r/r DLBCL. This hypothesis was supported by the results from a Phase 2 clinical study evaluating birelentinib monotherapy in r/r DLBCL, TAI-SHAN9, which was presented at the 2025 European Hematology Association ("**EHA**") Congress and the 18th ICML. Significant anti-tumor activities were observed in both GCB and non-GCB DLBCL subtypes.

Market Opportunities and Competitive Landscape

DLBCL is an aggressive malignancy arising from mature B cells and is characterized by diffuse infiltration of large, atypical B cells in lymph nodes or extranodal tissues, making it the most common subtype of NHL worldwide.

R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) remains the standard first-line treatment for newly diagnosed DLBCL and cures approximately 50-60% of patients. However, approximately 30-50% of patients experience primary refractory disease or relapse. Outcomes are particularly poor in high-risk subgroups, including patients with double-hit lymphoma ("**DHL**") or triple-hit lymphoma ("**THL**"). Although newer regimens

such as Pola-R-CHP (polatuzumab vedotin replacing vincristine in R-CHOP) have demonstrated improved efficacy in certain settings, a substantial proportion of high-risk patients continue to relapse early, underscoring the persistent unmet need for more effective first-line therapies.

In the relapsed or refractory setting, treatment strategies are stratified by patient eligibility. Salvage chemotherapy followed by autologous stem cell transplantation ("**ASCT**") is typically pursued for fit patients, while CAR-T cell therapies or targeted regimens may be used in transplant-ineligible patients or those who relapse after CAR-T therapy. Despite this expanding therapeutic landscape, outcomes remain poor for key high-risk populations, including patients with primary refractory or quick progressive disease, with DHL/THL genetics, or patients who failed prior CAR-T therapy or ASCT.

A major therapeutic limitation for BTKi in DLBCL is their narrow activity in the non-germinal center B-cell-like ("**non-GCB**") subtype only which accounts for approximately 40-50% of DLBCL cases. This highlights the inadequacy of BTK-only blockade and underscores the need for novel agents capable of delivering broad and durable efficacy across molecular subtypes by overcoming redundant survival pathways.

According to CIC, the global DLBCL drug market grew from US$3.3 billion in 2020 to US$6.0 billion in 2024 at a CAGR of 16.2%. It is projected to further expand to US$24.2 billion in 2035, representing a CAGR of 13.5% from 2024 to 2035. The market size in China increased from US$0.6 billion in 2020 to US$1.2 billion in 2024 at a CAGR of 20.7%, and is expected to reach US$4.6 billion in 2035, reflecting an 13.1% CAGR from 2024 to 2035.

The contemporary DLBCL market is dominated by biologics and cell therapies. There remains no approved small-molecule targeting Lyn/BTK or BCR signaling specifically for DLBCL, and no small-molecule has become a backbone therapy for either 1L or r/r disease. While a few BTK inhibitors show efficacy signals in non-GCB DLBCL, treatment coverage of GCB DLBCL is still underserved. This leaves significant space for differentiated oral agents capable of delivering broad and durable efficacy across DLBCL subtypes of both non-GCB DLBCL and GCB DLBCL.

For details, see "Industry Overview — The Oncology Therapeutics Market — The DLBCL Market."

Competitive Advantages

Meaningful single-agent activity in r/r DLBCL

Under current treatment paradigms, patients with r/r DLBCL have a poor prognosis. Against this backdrop, birelentinib monotherapy demonstrated clinically meaningful anti-tumor activity in its Phase 2 clinical study, TAI-SHAN9, reporting an ORR of 50% as a single agent. Importantly, birelentinib demonstrated activity in both the GCB and non-GCB subtypes of DLBCL, with comparable response rates across subgroups. These findings suggest the potential for broad therapeutic activity across molecularly distinct forms of DLBCL.

Expansion into first-line combination therapy

We are advancing birelentinib beyond the relapsed or refractory setting by evaluating it in first-line combination regimens for DLBCL, including combinations with established chemotherapy, such as R-CHOP, with the objective of improving outcomes by adding dual inhibition of B-cell receptor signaling pathways to standard frontline treatment.

More broadly, the dual inhibition of Lyn and BTK provides a mechanistic rationale for combining birelentinib with other targeted therapies or immune-active agents. This approach is intended to support synergistic regimens in diseases such as DLBCL and follicular lymphoma, where biological heterogeneity is substantial and suppression of multiple signaling pathways may be required to achieve durable disease control.

Summary of Clinical Trials and Development Plan

The following table sets forth an overview of the ongoing and planned clinical trials of birelentinib for DLBCL.

Study Name	Indication	Mono/Combo	Line of Treatment	Trial Phase	Trial Status	Primary Regions	(Planned) Start Date	(Planned) Data Readout Date
TAI-SHAN9	r/r DLBCL	Mono	2L/2L+	Phase 2	Ongoing	China	March 2024	Study completion in 3Q 2026
TAI-SHAN12	r/r DLBCL	Combo with immuno chemotherapy	1L/2L/ 2L+	Phase 1b/2	Ongoing	China	August 2025	Primary readout in 1Q 2026
TAI-SHAN19	DLBCL	Combo with R-CHOP	1L	Registrational Phase 3	Planned	China and United States	2H 2026	Primary readout in 2030

TAI-SHAN9

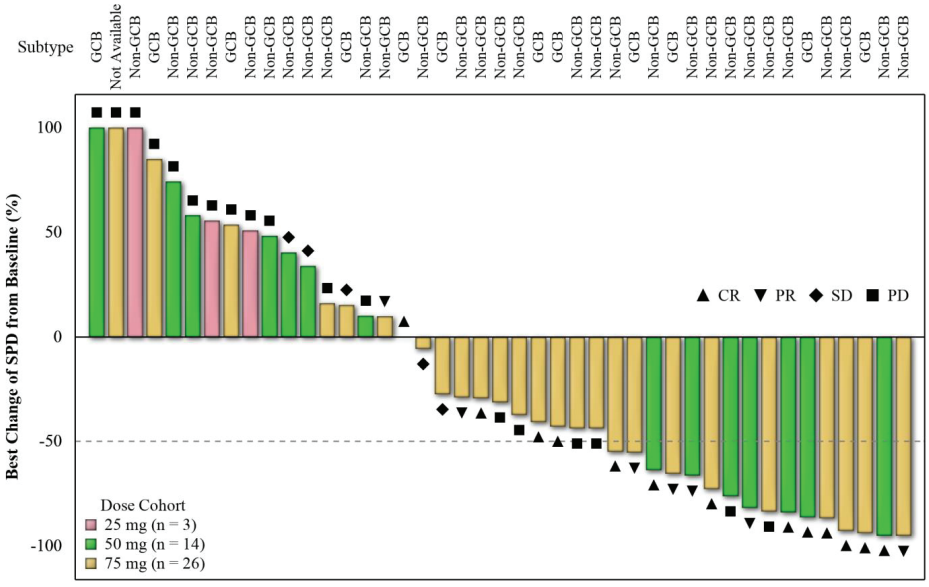
This is a Phase 2, open-label, multicenter study to evaluate the efficacy, safety, tolerability, and pharmacokinetic characteristics of birelentinib in patients with r/r DLBCL. This study consists of two parts: Part A: dose randomization and extension, and Part B: single arm study under RP2D.

Trial objectives. Primary objective of this trial is to evaluate the efficacy of birelentinib in patients with r/r DLBCL. Primary endpoint is ORR assessed by investigator per Lugano 2014 criteria. Secondary objectives are to evaluate safety, efficacy and pharmacokinetics of birelentinib in patients with r/r DLBCL. Efficacy endpoints include CRR, DoR, TTR, and PFS.

Efficacy results as of October 2025. In TAI-SHAN9, birelentinib showed encouraging activity in r/r DLBCL, reporting an ORR of 50% as a single agent and noting similar efficacy between GCB and non-GCB subtypes.

The waterfall plot below shows each patient with best change in tumor burden from baseline in r/r DLBCL across dose cohorts, with response categories annotated on the chart.

Waterfall Plot of Best Change in Tumor Burden From Baseline in r/r DLBCL



Note: CR: Complete Response; GCB: Germinal Center B Cell Like; Non GCB: Non Germinal Center B Cell; PR: Partial Response; SD: Stable Disease; PD: Progressive Disease; SPD: Sum of the Product of the Perpendicular Diameters.

n: Number of participants with at least one change of SPD in the analysis set for each treatment group.

Best percent change from baseline (%) for each participant was calculated as the smallest percent change from baseline (large st decrease) in SPD for target lesions. Positive values indicate tumor growth and negative values indicate tumor reduction.

Dashed line represents the threshold for partial response (50%).

The response shown in the figure represents the best overall response for each participant.

Tumor size assessments post the new anti cancer therapy or documented progressive disease were excluded from the calculation of best change in tumor size. SPD increase more than 100% is presented as 100%.

Source: Presentation at J.P. Morgan Healthcare Conference 2026

Safety results as of April 2025. Birelentinib was well tolerated up to 100 mg QD, with dose-dependent increase in the incidence of Grade 3 or above TRAEs. The most common Grade 3 or above TRAE was thrombocytopenia, and the majority of patients suffering Grade 3 or above TRAEs could recover within one week. There were no reports of atrial fibrillation or significant bleeding. Dose reduction and discontinuation occurred in 2.4% and 2.4% of patients, respectively. There were no deaths as a result of TEAE.

Trial status. We initiated this Phase 2 trial in March 2024, and expect to complete this trial in the third quarter of 2026.

TAI-SHAN12

This is a Phase 1b/2, multicenter study evaluating the efficacy and safety of birelentinib combined with immunochemotherapy in patients with r/r DLBCL. This study consists of 3 arms including birelentinib in combination with R-CHOP, R-GemOx or BR per standard dosing, in 21-day cycles.

Trial objectives. The primary objective for Part A was to evaluate the safety of combination therapy. The primary objective for Part B was to evaluate the efficacy by investigator evaluated ORR according to Lugano 2014 criteria. Other efficacy endpoints included CRR, TTR, DoR, PFS and OS.

Trial status. We initiated this Phase 1b/2 trial in August 2025 and expect to obtain primary readout for this trial in the second quarter of 2026.

TAI-SHAN19

TAI-SHAN19 is a planned Phase 3, randomized, double-blind, multi-center study of birelentinib combined with R-CHOP as first-line treatment in patients with DLBCL. We plan to submit an IND for this trial in the first quarter of 2026 and initiate this trial in the second half of 2026 following the IND approval.

Primary ITP

The dual-pathway coverage of birelentinib may be beneficial to address immune-mediated diseases such as ITP, where pathogenic autoantibody production by B cells and Fc receptor-mediated platelet destruction by macrophages are driven by BTK- and Lyn-dependent signaling cascades. By targeting both kinases, birelentinib provides a mechanistic rationale for evaluation in ITP. We are assessing birelentinib in an ongoing Phase 2 clinical trial, TAI-SHAN11, for r/r primary ITP in China.

Market Opportunities and Competitive Landscape

Primary ITP has several unmet clinical needs driven by its chronic, unpredictable course and the need for durable disease control without excessive treatment burden. First-line steroids/IVIG can raise platelets quickly, but many patients relapse and steroids cause significant toxicity with repeated use. In r/r ITP, TPO-based therapies can be effective but commonly require continuous treatment, may have long-term safety concerns, and cost/access issues. Overall, there is a need for safer, more practical options that deliver sustained platelet responses and reduce steroid dependence. For details, please refer to "— Our Product Portfolio — Golidocitinib — A Commercialized, Next-generation, Highly Selective JAK1 Inhibitor — Primary ITP — Market Opportunities and Competitive Landscape."

Summary of Clinical Trials

The following table sets forth an overview of the ongoing clinical trial of birelentinib for primary ITP.

Study Name	Indication	Mono/Combo	Line of Treatment	Trial Phase	Trial Status	Region	(Planned) Start Date	(Planned) Data Readout Date
TAI-SHAN11 . . .	r/r primary ITP	Mono	2L/2L+	Phase 2	Ongoing	China	January 2026	Primary readout in 1H 2027

TAI-SHAN11

This is a Phase 2 study evaluating the efficacy and safety of birelentinib in adults with r/r primary ITP.

Trial design. The target population of this study is patients with primary ITP who had failed to respond or relapsed after receiving at least one standard therapy. Participants who meet the inclusion criteria and do not meet the exclusion criteria are randomized to three dose groups (birelentinib 25 mg once every other day, birelentinib 25 mg once daily, and birelentinib 50 mg once daily) in a 1:1:1 ratio. The stratification factor is baseline platelet count ($\geq 15\times10^9$/L or $<15\times10^9$/L).

Trial objectives. The primary endpoint for this trial is ORR at 4 weeks which is the proportion of participants who achieve platelet counts $\geq 50\times10^9$/L on 2 consecutive occasions (separated by at least 7 days) during the first 4 weeks of treatment.

Trial status. We initiated this Phase 2 trial in January 2026 and expect to obtain primary readout in the first half of 2027.

DZD6008 — A Novel, Highly Selective, BBB-penetrant, Fourth-generation EGFR TKI

Overview

DZD6008 is a fourth-generation EGFR TKI designed to address clinical challenges after treatment failure from a third generation EGFR TKI such as osimertinib (Tagrisso®). Patients with sensitizing mutations and relapsed from 3rd generation EGFR TKI face limited treatment options. One of the most dominant resistance mechanisms is the C797X mutation, which prevent covalent inhibitors, such as Osimertinib, binding to its target. CNS is often the 1st site of relapse, suggesting poor BBB-penetration capability of the existing EGFR inhibitors. DZD6008 was designed to address these challenges.

In preclinical models, DZD6008 exhibits potent and consistent inhibitory activity across a broad range of EGFR mutations, including EGFR driver mutations (L858R and exon 19 deletions), resistant double mutations (including T790M/C797S in the context of L858R or exon 19 deletion), and the challenging triple mutations (C797X plus T790M plus L858R or exon 19 deletion). DZD6008 has more than 50-fold selectivity versus wild-type EGFR, and thus provides large safety margin with minimizing wildtype EGFR associated toxicities. With no measurable activities against a panel of ion channels, DZD6008 is expected to have low cardiotoxicity risk have that has been associated with certain third-generation EGFR TKIs.

In addition, DZD6008 is designed to fully penetrate the blood-brain barrier and has demonstrated complete inhibition of tumor growth across multiple EGFR-mutant tumor cell lines and animal models. These properties have been quickly validated in early clinical studies.

In TIAN-SHAN1 and TIAN-SHAN2, the Phase 1/2 clinical studies evaluating DZD6008 monotherapy in EGFR-mutant NSCLC patients conducted in the United States/Australia and China, respectively, early clinical data demonstrated encouraging anti-tumor activity, good tolerability, and clinically meaningful tumor shrinkage in a heavily pre-treated NSCLC population with heterogeneous EGFR-mutations, including those with CNS metastases. In patients with C797X mutations, the ORR was 60% at 60 mg, regardless of prior lines and types of therapies, and the mPFS was >10 months as of January 2025. Moreover, DZD6008 demonstrated high blood-brain barrier penetration, with the ratio of free drug concentration in cerebrospinal fluid ("**CSF**") and plasma slightly over 1.0 consistent with observed clinical efficacy in patients with CNS metastases.

Drug Design and Mechanism of Action

DZD6008 utilizes a novel EGFR binding mode that does not depend on the C797 residue for binding, thereby overcoming the C797X resistance mutation. It employed optimized non-covalent interactions to occupy the ATP-binding pocket with high affinity even in the presence of triple mutations. It is also designed with a specific steric fit that creates an over 50-fold selectivity window for mutant EGFR over wild-type EGFR, sparing the wild-type receptor in normal tissues and thereby minimizing wildtype EGFR-driven toxicities.

Furthermore, DZD6008 has been structurally optimized to exhibit low affinity for efflux transporters, effectively evading the active transport mechanisms that typically restrict the blood-brain barrier penetration of other EGFR TKIs. Clinical PK data from the TIAN-SHAN2 study validates this design, demonstrating that the drug attains concentrations in the central nervous system equal to or exceeding those in the systemic circulation, a characteristic that supports its potential to induce deep intracranial tumor regression and provides a critical therapeutic alternative for patients with CNS metastases.

Market Opportunities and Competitive Landscape

EGFR mutations are the most frequent driver mutations in NSCLC. However, patients with EGFR-mutant NSCLC often face resistance to EGFR TKI treatments. For EGFR TKI–resistant NSCLC patients, the current standard of care is chemotherapy, which offers limited benefit, with patients receiving the therapy achieving an average ORR of 25% to 29%, mPFS of less than six months. These benchmarks underscore why a next-generation EGFR TKI that can overcome resistance while preserving tolerability could represent an important step forward for patients whose disease has progressed on prior targeted therapies.

Additionally, over 2.5 million patients globally develop CNS metastases from tumors each year, with advanced lung cancer patients experiencing the highest rates of brain metastasis. For NSCLC patients who progress after receiving third-generation EGFR TKI treatment, CNS metastases and acquired EGFR resistance mutations are common challenges.

According to CIC, the global EGFR-mutant NSCLC drug market, which encompasses NSCLC harboring classical mutations (not including exon20ins or PACC mutations), grew from US$8.1 billion in 2020 to US$11.0 billion in 2024 at a CAGR of 8.0%. It is projected to further expand to US$24.7 billion in 2035, representing a CAGR of 7.7% from 2024 to 2035.

For details, see "Industry Overview — The Oncology Therapeutics Market — The EGFR-mutant NSCLC Market."

Competitive Advantages

Broad-spectrum mutation coverage for sustained efficacy

DZD6008 is positioned as a broad-spectrum resistance solution because it is designed to inhibit mutation types that are not adequately addressed by prior generations of EGFR TKIs. This breadth is central to its clinical value proposition: rather than targeting a narrow resistance niche, DZD6008 is intended to address a wider set of post-treatment mutations patterns that can arise across from different TKI treatment sequence. By covering classical driver mutations, double-resistance and triple-resistance mutations, it seeks to meet the pressing clinical needs with a single oral targeted drug capable of addressing heterogeneous resistance mechanisms.

In later-line monotherapy for EGFR TKI–resistant patients, early clinical data from TIAN-SHAN1 and TIAN-SHAN2 studies showed encouraging anti-tumor activity in heavily pretreated patients (median of 4.5 prior lines of therapy, ranging from 2 to 8) across diverse EGFR mutation types as well as treatment-naïve EGFR-mutant NSCLC patients. In patients with C797X mutations, the ORR was 60% at 60 mg, regardless of prior lines and types of therapies, and the mPFS was >10 months as of January 2026.

Full blood-brain barrier penetration

DZD6008 is also designed to achieve full blood-brain penetration, enabling it to target CNS metastases most efficiently. Clinical PK data from the TIAN-SHAN2 demonstrates that DZD6008 attains concentrations in the central nervous system equal to or exceeding those in the systemic circulation. This attribute is clinically significant because intracranial disease progression is often the first reason for treatment failures even when extracranial disease appears under control.

Mechanism based combination with in-house ZEGFROVY® to enhance our competitive strength in EGFR mutation driven disease.

ZEGFROVY® is a potent inhibitor of identified resistance mutations to DZD6008. DZD6008 is designed to inhibit EGFR C790X mutation, which is the dominant resistant mutation to ZEGFROVY®. It has been noticed clinically that patients with L858R mutation benefit less from third generation EGFR TKI treatment due to its higher tendency to develop complex resistant mutations, which are highly sensitive to ZEGFROVY®. These findings form the scientific rationale to combine DZD6008 with ZEGFROVY® as an all oral combinational regime. This option is being actively evaluated in our ongoing clinical studies, especially in the first line setting where an all oral, chemo-free, targeted therapy offers clear advantages over FLAURA2 (Osimertinib combined with chemo doublet) and MARIPOSA (cMet-EGFR bi-specific antibody combined with a third generation EGFR TKI).

For details, see "— Our Pipeline — ZEGFROVY® — A globally competitive, commercialized EGFR TKI — In Combination with DZD6008 for EGFR-mutant NSCLC."

Favorable Safety Profile in Clinical Trials

As illustrated in the following table, DZD6008 monotherapy from 20 mg to 90 mg demonstrated favorable safety profile in clinical trials, with the incidences of all grade and higher than grade 3 diarrhea, rash and paronychia lower than those reported by Tagrisso®, the market leader among the third-generation EGFR TKI. This favorable safety profile is a critical advantage for treating earlier disease where tolerability is often the most important consideration. It also decreases the potential additive or synergistic toxicities often associated with combinational therapies. Taking advantage of this, we are actively evaluating DZD6008 in combination with ZEGFROVY® as an all oral combination option.

Incidence of AEs of Special Interests for DZD6008 and Marketed EGFR TKI

	DZD6008 20 mg (N = 7) n (%)		DZD6008 40 mg (N = 69) n (%)		DZD6008 60 mg (N = 79) n (%)		DZD6008 90 mg (N = 11) n (%)		*Tagrisso 80 mg (N=337) n (%)	
	All Grades	Grade ≥ 3	All Grades	Grade ≥ 3	All Grades	Grade ≥ 3	All Grades	Grade ≥ 3	All Grades	Grade ≥ 3
Diarrhea	14.3%	0.0%	14.5%	0.0%	17.7%	1.3%	18.2%	0.0%	47.0%	2.4%
Rash	0.0%	0.0%	15.9%	0.0%	13.9%	0.0%	18.2%	0.0%	40.0%	0.6%
Paronychia	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	37.0%	0.9%

Source: Presentation at J.P. Morgan Healthcare Conference 2026; Tagrisso USPI (2024.2)

Summary of Clinical Trials and Development Plan

The following table sets forth an overview of the ongoing and planned clinical trials of DZD6008.

Study Name	Indication	Mono/Combo	Line of Treatment	Trial Phase	Trial Status	Primary Regions	(Planned) Start Date	(Planned) Data Readout Date
TIAN-SHAN1	Advanced EGFR-mutant NSCLC	Mono	1L/2L/2L+	Phase 1/2	Ongoing	U.S., Australia	May 2025	Dose escalation data readout in 2Q 2026
TIAN-SHAN2	Advanced EGFR-mutant NSCLC	Mono	1L/2L/2L+	Phase 1/2	Ongoing	China	June 2024	Phase 2 data readout in 2Q 2026
TIAN-SHAN7	Advanced EGFR-mutant NSCLC	Combo with chemotherapy	2L/2L+	Phase 2	Ongoing	China	July 2025	Primary readout in 2Q 2026
TIAN-SHAN8	Advanced EGFR-mutant NSCLC	Combo with ZEGFROVY®	1L/2L/ 2L+	Phase 1/2	Ongoing	China	July 2025	Primary readout in 3Q 2026
TIAN-SHAN16	EGFR-mutant NSCLC	Combo with ZEGFROVY®	1L	Registrational Phase 3	Planned	China	1H 2027	NDA submission in 2029

TIAN-SHAN1 and TIAN-SHAN2

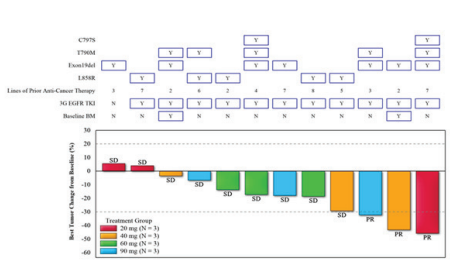
TIAN-SHAN1 is a multinational Phase 1/2, open-label study of DZD6008 for advanced EGFR-mutant NSCLC, conducted in the U.S. and Australia. TIAN-SHAN2 is a Phase 1/2 study with the similar design, conducted in China. These are standard first-in-human studies with dose escalation in previously treated patients. Food effect is also assessed as part of the study.

Trial status. We initiated TIAN-SHAN1 in May 2025 and expect to obtain data readout for the escalation stage in the second quarter of 2026. We initiated TIAN-SHAN2 in June 2024, obtained Phase 1 (Part A) data readout in March 2025 and expect to obtain Phase 2 (Part B) data readout in the second quarter of 2026.

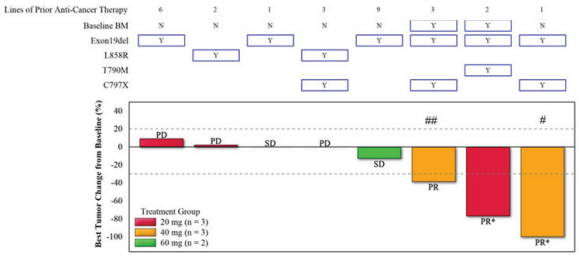
Efficacy results as of January 2026. As of January 2026, in patients with C797X mutations enrolled in TIAN-SHAN1 and TIAN-SHAN2 studies, the ORR was 60% at 60 mg, regardless of prior lines and types of therapies, and the mPFS was over 10 months as of January 2026. DZD6008 also demonstrated clear penetration of the blood-brain barrier, with the cerebrospinal fluid drug concentrations slightly exceeding free plasma concentrations, supporting its potential to address intracranial disease.

The waterfall plots below show the best percentage change from baseline in tumor size for each patient in TIAN-SHAN1 and TIAN-SHAN2, respectively.

Waterfall Plot of Best Tumor Change



China cohort (TIAN-SHAN1)

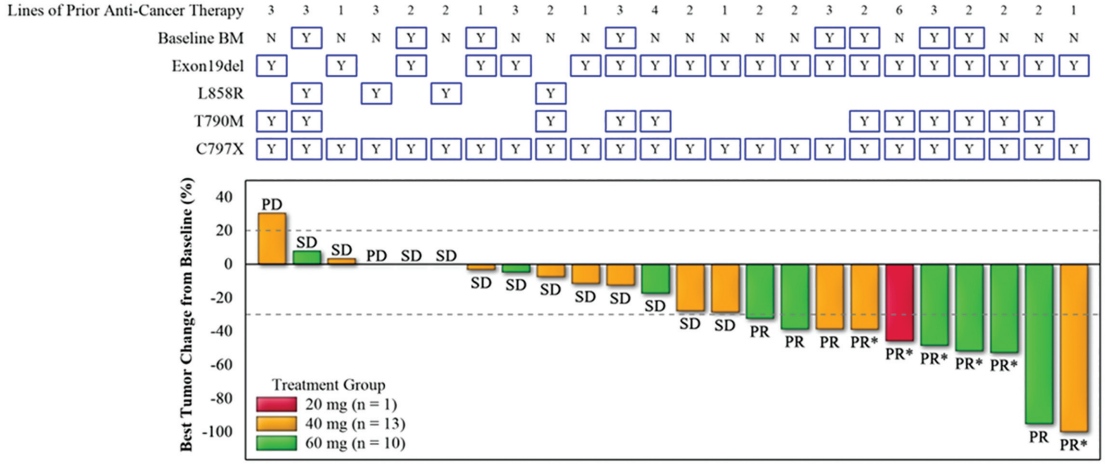


Ex-China cohort (TIAN-SHAN2)

Source: Presentation at J.P. Morgan Healthcare Conference 2026

The waterfall plot below shows the best percentage change from baseline in tumor size for each patient with C797X mutation in the monotherapy cohort, illustrating the distribution of tumor shrinkage and progression across dose groups.

Best Tumor Size Change in Patients with C797X Mutations



Note: CR: Complete Response; N: Number of participants in the analysis set for each treatment group; PD: Progressive Disease; PR: Partial Response; SD: Stable Disease.

*Best percent change from baseline (%) for each participant was calculated as the smallest percent change from baseline (largest decrease) in sum of the longest diameter ("**SLD**") for target lesion. Positive values indicate tumor growth and negative values indicate tumor reduction.*

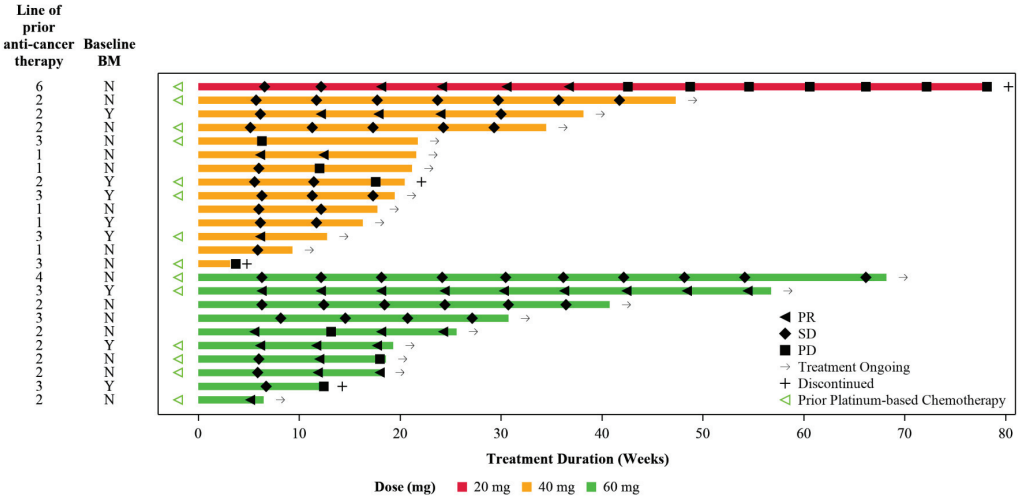
Dashed lines represent the threshold for progressive disease (20%) and partial response (-30%).

*Best overall response was displayed in the plot, * was a confirmed response.*

Source: Presentation at J.P. Morgan Healthcare Conference 2026

The swimmer plot below shows treatment duration over time for individual patients with C797X mutations in the monotherapy cohort, with response status annotated to visualize durability on treatment.

Treatment Duration and Response Status in Patients with C797X Mutations

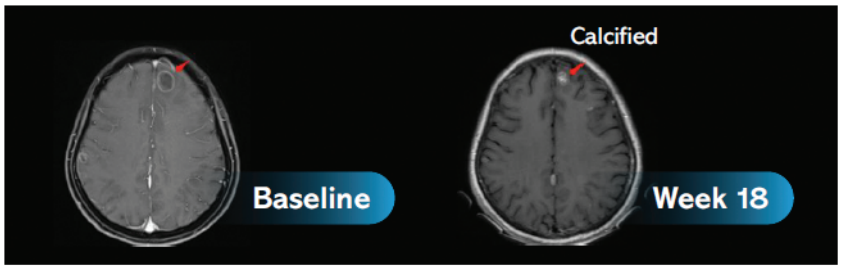


Note: CR: Complete Response; PD: Progressive Disease; PR: Partial Response; SD: Stable Disease.

Source: Presentation at J.P. Morgan Healthcare Conference 2026

The paired brain imaging panels below illustrate an example of partial response of the intracranial tumor, comparing baseline with the Week 18 assessment in a patient who had not received prior radiotherapy.

Baseline vs. Week 18 Brain Imaging Demonstrating Intracranial Partial Response (No Prior Radiotherapy)



Source: Presentation at J.P. Morgan Healthcare Conference 2026

TIAN-SHAN7

This is a Phase 2, open-label, multicenter study to assess the safety, tolerability, pharmacokinetics, and anti-tumor efficacy of DZD6008 in combination with chemotherapy in patients with EGFR-mutant locally advanced or metastatic NSCLC in China.

Trial design. This study includes Part A and Part B. In Part A, EGFR TKI pretreated patients will be enrolled into A1 cohort (DZD6008 combined with pemetrexed and carboplatin) and A2 cohort (DZD6008 combined with docetaxel).

In Part B, treatment-naïve patients with locally advanced or metastatic NSCLC with classical EGFR mutations will be enrolled and receive DZD6008 combined with carboplatin and pemetrexed treatment at selected dose.

Participants will receive repeated daily dosing of DZD6008, and chemotherapy (upon enrolled cohort) every 3 weeks, until disease progression, intolerable AEs, discontinuation criteria are met, withdrawal of consent, or study termination.

Trial status. We initiated this Phase 2 trial in July 2025 and expect to obtain primary readout for this trial in the second quarter of 2026.

TIAN-SHAN8 and TIAN-SHAN16

For details about TIAN-SHAN8 and TIAN-SHAN16 assessing the combination therapy of DZD6008 and ZEGFROVY®, see "— Our Pipeline — ZEGFROVY® — A globally competitive, commercialized EGFR TKI — In Combination with DZD6008 for EGFR-mutant NSCLC."

GW5282 — A Next-generation EZH1/2 Dual Inhibitor

Overview

GW5282 is a next-generation EZH1/2 (Enhancer of Zeste Homolog 1 and 2) dual inhibitor. This molecule has a dual-target mechanism, simultaneously inhibiting EZH1 and EZH2 with equal potency, which prevents the tumor from utilizing a compensatory activation pathway to escape treatment.

EZH2 is a clinically validated target for multiple hematological and solid tumors. Our translational science research showed that inhibiting EZH2 alone could not completely block the pathway as the EZH1, the other closely related gene family member, often compensates EZH2 activity. Approved EZH1-only inhibitors suffer from another deficiency, too short human blood half-life. Consequently, a much higher dose is necessary in order to cover the target, which causes typical high dose-related bone marrow toxicities. GW5282 stands out as a next-generation therapy that addresses the key limitations of these existing EZH2-only inhibitors. GW5282 was designed to inhibit both EZH1 and EZH2 with equal potencies but spare other non-targeting genes. Available clinical data fully validated our molecular design properties, including a longer half-life, improved absorption and oral bioavailability, and much lower bone marrow toxicities. With these improvement, we are able to reduce the patient's pill burden from over 14 pills to just one or two pills daily, enhancing patient compliance. Our strategic focus for this molecule is directed toward solid tumors, including lung cancer, for which we have validated preclinical evidence.

We are developing GW5282 for the treatment of r/r NHL as well as solid tumors, including prostate cancer, lung cancer, ovarian and endometrial cancers.

r/r NHL

In many NHL, EZH2 is abnormally high or hyperactive, leading to excessive H3K27me3 and inappropriate silencing of genes that normally restrain tumor growth, which is why elevated EZH2 is often linked with worse outcomes. In follicular lymphoma ("**FL**") and DLBCL, gain-of-function EZH2 mutations further increase this gene-silencing activity, driving abnormal repression of target genes, promoting stem-cell-like programs, and supporting malignant transformation. As a result, blocking EZH2 has emerged as a promising anti-cancer strategy to reduce aberrant H3K27 methylation and re-enable suppressed tumor-control pathways.

GW5282 significantly reduce H3K27me3 levels in cells and demonstrates strong anti-tumor activity across NHL models in both in vitro and in vivo preclinical models. GW5282 is currently in Phase 1/2 clinical study to assess its safety, tolerability, pharmacokinetics, and anti-tumor efficacy in patients with r/r NHL in China. Tumor shrinkage was observed at the starting dose of 40mg, twice daily ("**BID**"). At this dose, more than 90% inhibition of the pharmacodynamic marker was achieved. No dose-limiting toxicities were observed up to 120mg, BID.

Market Opportunities and Competitive Landscape

Lymphoma is a group of malignant tumors originating from lymphocytes. It is mainly characterized by painless lymph node enlargement, hepatosplenomegaly, and involvement of various organs throughout the body, accompanied by symptoms such as fever, night sweats, and unexplained weight loss. Lymphomas are classified into NHL and Hodgkin lymphoma ("**HL**"), with NHL accounting for about 80-90%. r/r NHL patients are often resistant to multiple lines of therapy, especially those resistant to targeted drugs (for example, BTK, BCL2 inhibitors). Salvage options are limited and toxic, with a median overall survival of only 6-12 months.

Competitive Advantages

A highly selective and potent EZH1 and EZH2 dual inhibitor. Apart from Valemetostat, which is approved only in Japan for the treatment of r/r ATL and r/r PTCL, no other EZH1/2 inhibitors have been approved globally for the treatment of r/r NHL. GW5252 exhibits similar and potent inhibition of EZH1 and EZH2, as well as various gain-of-function mutations in EZH2, which may potentially overcome the insufficient efficacy of EZH2-only inhibitors due to compensatory activation of EZH1.

Excellent methyltransferases selectivity. Among 36 human methyltransferases, GW5282 exhibits high selectivity, specifically inhibiting only EZH1 and EZH2, which holds promise for reducing off-target toxicity in the clinic.

Favorable DMPK profiles differentiate GW5282 from other EZH inhibitors. Nearly completed (>90%) pharmacodynamic biomarker (H3K27me3) modulation was achieved at the starting dose of GW5282 40 mg BID.

Summary of Clinical Trial and Development Plan

The following table sets forth an overview of the ongoing clinical trial of GW5282 for r/r NHL.

Study Name	Indication	Monotherapy/ Combination Therapy	Line of Treatment	Trial Phase	Trial Status	Region	Start Date	Next milestone
BEI-DOU1	r/r NHL	Monotherapy	r/r	Phase 1/2	Ongoing	China	June 2025	Determining RP2D in 2Q 2026

BEI-DOU1

This is a Phase 1/2, open-label, multicenter study to evaluate the safety, tolerability, pharmacokinetic characteristics, and anti-tumor efficacy of GW5282 in patients with r/r NHL.

Trial design

This is a first-in-human ("**FIH**") study targeting patients with r/r NHL. The study will initially utilize a BOIN design to determine the safe dosage range of GW5282 monotherapy in the NHL patients and preliminarily identify the recommended dose. Subsequently, the cohort will be expanded at this selected dose to further assess the efficacy of GW5282 monotherapy in r/r NHL.

Trial objectives

The study objectives include (i) to evaluate the safety and tolerability of GW5282 in patients with NHL, (ii) to characterize the PK profile of GW5282 after single and multiple dosing, (iii) to perform a preliminary assessment of the anti-tumor activity of GW5282 in patients with NHL.

Trial status

We initiated this trial in June 2025 and expect to determine RP2D in the second quarter of 2026.

Solid tumors

We are developing GW5282 for the treatment of solid tumors, including prostate cancer, lung cancer, ovarian and endometrial cancers.

Market Opportunities and Competitive Landscape

Prostate cancer is a major cancer for male worldwide and its prevalence is rising in China. When existing treatments fail, patients face ongoing progression and a high risk of bone metastases, creating strong unmet clinical need.

Lung cancer is the most common cancer worldwide. Lung cancer patients with driver mutations are mainly treated with targeted tyrosine kinase inhibitors, while those without driver mutations rely on chemotherapy, anti-angiogenic drugs, or immunotherapy. Even though immunotherapy has improved outcomes, many patients still progress within about a year, and there is currently no globally approved standard treatment after immunotherapy resistance.

Ovarian and endometrial cancers also see significant unmet needs: despite options such as immune checkpoint inhibitors and PARP inhibitors, relapse and drug resistance are common, leading to poor prognosis and low 5-year survival. As a result, novel therapies for these solid tumors are urgently needed.

A promising approach focuses for these solid tumors on the epigenetic regulator EZH2, the catalytic core of the PRC2 complex that drives H3K27 trimethylation and abnormal gene silencing in cancer.

This biology is relevant across several solid tumors. In castration-resistant prostate cancer, EZH2 activity appears to promote progression, and early clinical data suggest that combining an EZH2 inhibitor (mevrometostat) with enzalutamide can benefit patients whose disease is resistant to abiraterone or enzalutamide. In lung cancer, preclinical studies suggest EZH2 inhibition may increase sensitivity to certain chemotherapies and reduce tumor growth in specific mutation contexts. In gynecologic cancers, ARID1A mutations are frequent in ovarian clear cell and endometrioid tumors, SMARCA4 mutations are common in SCCOHT, and EZH2 or EZH1/2 inhibition has shown synthetic-lethal effects in models, with early clinical signals of anti-tumor activity in patients carrying these alterations.

Competitive Advantages

Optimized PK properties for improved compliance

One of the key advantages of GW5282 is its longer half-life, which addresses a significant flaw in many existing EZH2-only inhibitors. Some current EZH2-only inhibitors require patients to take multiple pills daily due to poor pharmacokinetic profiles. In contrast, the pharmacokinetics of GW5282 is expected to reduce the daily pill count from more than 14 tablets to just one or two, which may improve treatment adherence, enhancing both convenience and the potential for sustained efficacy over time.

Summary of Clinical Trial and Development Plan

The following table sets forth an overview of the planned clinical trial of GW5282 for advanced solid tumors.

Study Name	Indication	Monotherapy/ Combination Therapy	Line of Treatment	Trial Phase	Trial Status	Region	Planned Start Date	Next milestone
BEI-DOU2	Solid tumors	Monotherapy	r/r	Phase 1/2	Ongoing	China	January 2026	Determining RP2D in 3Q 2026

BEI-DOU2

This is a Phase 1/2, open-label, multicenter study to evaluate the safety, tolerability, pharmacokinetic characteristics, and anti-tumor efficacy of GW5282 in patients with advanced solid tumors.

Trial design. This study will enroll patients with advanced solid tumors who have progressed on, or are intolerant to, standard therapy. The study will initially employ a BOIN design to determine the safe dosage range of GW5282 monotherapy and to identify a preliminary recommended dose. The cohort will subsequently be expanded at this dose level to further observe the efficacy of GW5282 monotherapy in patients with advanced solid tumors.

Trial objectives. The study objectives include (i) to evaluate the safety and tolerability of GW5282 in patients with advanced solid tumors and to determine the MTD and the recommended dose(s), (ii) to characterize the PK profile of GW5282 following single and multiple doses, and (iii) to perform a preliminary assessment of the anti-tumor activity of GW5282 in patients with advanced solid tumors.

Trial status. We initiated this trial in December 2025 and expect to determine RP2D in the third quarter of 2026.

DZD1516 — A Highly Selective HER2 TKI that Addresses CNS Metastases and Loss of HER2 Extracellular Domain

DZD1516 is an orally available, reversible, and highly selective small-molecule HER2 TKI that addresses some of the most pressing challenges in treating HER2-positive breast cancer, particularly in patients with CNS metastases and those experiencing HER2 loss. By providing a novel mechanism of action and enhanced CNS penetration, DZD1516 represents a promising therapeutic approach for patients who have limited treatment options with current therapies.

A significant clinical challenge in HER2-positive breast cancer is the high rate of CNS metastases, affecting 50-60% of advanced breast cancer patients. CNS metastasis in HER2-positive breast cancer is associated with poor prognosis, as many current therapies are unable to effectively treat tumors that spread to the brain.

A critical differentiator for DZD1516 is its ability to cross the blood-brain barrier, a major hurdle in treating CNS metastases. In preclinical studies, DZD1516 demonstrates robust penetration into the brain, positioning it as a highly promising option for treating HER2-positive breast cancer patients with CNS metastases. This unique capability gives DZD1516 the potential to address both systemic disease and CNS metastases in a way that current therapies cannot.

Another challenge in treating HER2-positive breast cancer is the phenomenon of loss of HER2 extracellular domain. Tumor cells may lose expression of HER2 extracellular domain due to drug acquired or de novo HER2 extracellular domain mutations, rendering antibody-based therapies ineffective. This further complicates the treatment of patients who initially respond to HER2-targeted therapies but later develop resistance.

Unlike antibody-based therapies that rely on binding to HER2 excellular domain, DZD1516 functions on intracellular kinase domain, which is not affected by loss of HER2 extracellular domain, making it a promising treatment option for cases of lose of HER2 extracellular domain. This mechanism of action allows DZD1516 to remain effective even when tumor cells no longer respond to antibody-based therapies, addressing a significant gap in current treatment options.

We plan to initiate a Phase 2, multicenter, randomized controlled study to evaluate the safety, tolerability, and anti-tumor activity of DZD1516 in combination with trastuzumab emtansine (T-DM1) in patients with metastatic HER2 positive (HER2+) breast cancer.

DZD2269 — A Highly Selective A2aR Antagonist

DZD2269 is an innovative, highly selective adenosine A2a receptor ("**A2aR**") antagonist. As of the Latest Practicable Date, there were no approved A2aR antagonists globally.

Adenosine, an endogenous immunosuppressive molecule, is typically present at low concentrations in normal tissues or blood. However, in the tumor microenvironment ("**TME**"), its concentration can be elevated by more than 1,000 times.

Preclinical and clinical studies indicate that DZD2269 effectively blocks adenosine/A2aR-mediated signaling pathways in a dose-dependent manner. A Phase 1 clinical trial of DZD2269 conducted in healthy volunteers demonstrated that DZD2269 can successfully inhibit the activation of these pathways. Importantly, at a dose of 160 mg, no drug-related adverse effects were observed, and the drug exhibited favorable safety and tolerability profiles. These early clinical findings support the continued clinical development of DZD2269 for use in oncology, where the A2aR pathway plays a significant role in immune suppression within the TME.

We completed a Phase 1, open-label, multicenter study to assess the safety, tolerability, pharmacokinetics and anti-tumor efficacy of DZD2269 in patients with metastatic castration resistant prostate cancer and a Phase 1 randomized, double-blind, placebo-controlled study to assess the safety, tolerability, and pharmacokinetics of DZD2269 oral tablet following single and multiple ascending dose administration in healthy adult participants. We plan to initiate combination study of DZD2269 in the second half of 2027.

RESEARCH AND DEVELOPMENT

We recognize that research and development are vital to our future growth and maintaining a competitive edge in the global biopharmaceutical industry. Leveraging our proprietary translational science research capabilities, we explore intricate biological pathways, potential drug targets and disease etiology to pursue source innovation-driven research and development, with the objective of delivering first-in-class medicines and breakthrough therapeutic modalities. We have established an integrated R&D platform with comprehensive in-house capabilities spanning the entire innovative drug development continuum, from early discovery through late-stage development. Our capabilities encompass drug target discovery and mechanism validation, translational science research, molecular design and compound screening, preclinical studies, chemistry, CMC, as well as clinical trial design and execution.

Our research and development capabilities are exemplified by our highly skilled and experienced R&D team, which is led by distinguished scientists and clinicians, including Dr. Zhang, our CEO, who has over 25 years of experience and is considered an influential figure in China's pharmaceutical industry. We conduct research and development activities primarily through our in-house R&D team and engage CROs from time to time to support our preclinical research and clinical trials. Our R&D capabilities are demonstrated by a strong portfolio of issued patents and patent applications in China and around the globe. For details, see "— Intellectual Property Rights" and Appendix VI to this document. In line with our commitment to innovation and technology breakthroughs, we invested heavily in R&D activities. For the years ended December 31, 2023, 2024 and the nine months ended September 30, 2024 and 2025, our research and development expenses amounted to RMB805.6 million, RMB723.7 million, RMB567.7 million and RMB644.2 million, respectively, accounting for 64.8%, 54.6%, 56.3% and 54.3% of our operating expenses, respectively.

Integrated Platform

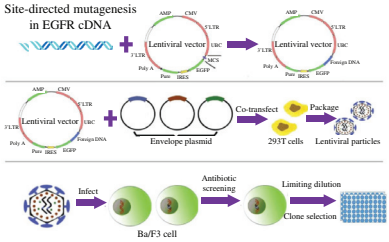
We attribute the strength of our product portfolio to the integrated technology platform that we have continued to strengthen over the eight years since our inception. We operate this platform under a disciplined, hypothesis-driven framework that is applied consistently across programs. We set clear "Go — No Go" criteria tied to clinical and translational milestones. This approach allows us to invest resources only in programs that show a strong scientific rationale and a realistic opportunity to achieve global first-in-class or best-in-class differentiation.

Our integrated technology platform seamlessly connects translational science, precision molecular design, and predictive clinical pharmacology into a unified workflow.

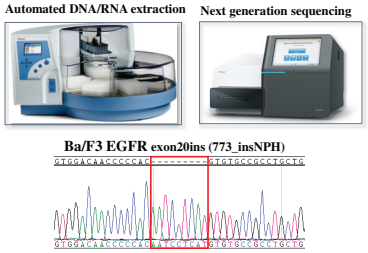
Translational science. We leverage a comprehensive library of over 1,500 cell lines, alongside proprietary disease models that best mimic human diseases with defined biological relevance. These models encompass transgenic and driver-mutation validation models, surgical CNS metastasis models with an intact BBB, and a short oral absorption model designed for rapid DMPK readouts. By utilizing these models and a variety of technologies, including cell engineering, sequencing, and high-throughput screening, we can accurately predict clinical activities and meticulously validate the intricate relationship between targets and diseases. These capabilities enable us to define a clear candidate drug target profile, as well as to identify and validate predictive biomarkers that guide patient selection, response prediction, and safety monitoring. It has played a pivotal role in programs such as ZEGFROVY® and golidocitinib, where translational data directly linked molecular mechanisms to disease pathology, enabling informed candidate selection and early go/no-go decision-making. The following graphic sets forth the features of our translational science platform.

Translational Science Platform

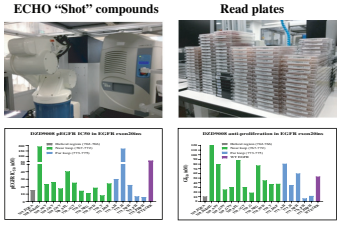
Cell Engineering



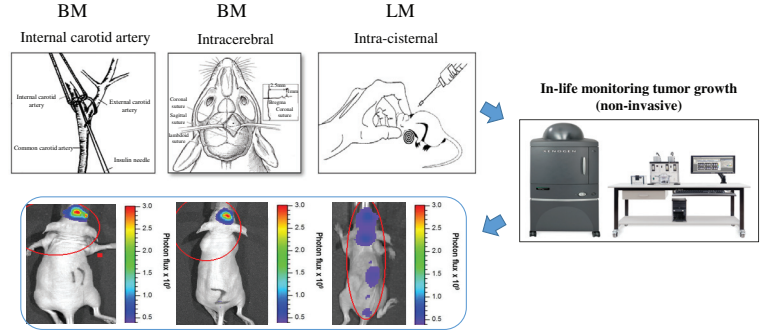
Sequencing



High Throughput Screening

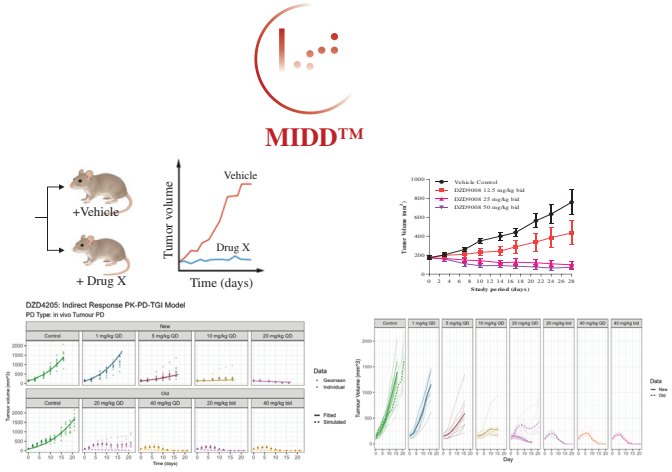


Brain metastasis



Precision molecular design. We transform the candidate drug target profiles defined by translational research into optimized molecular entities through structure-based and computer-aided design methodologies. Combining extensive medicinal chemistry expertise with advanced modeling and simulation tools, we have precise control over multiple design parameters, including potency, selectivity, safety, and full blood-brain barrier penetration. By iteratively refining molecular scaffolds, we achieve balanced pharmacokinetic and pharmacodynamic profiles and improved developability. This precision-engineering approach has been instrumental in advancing differentiated products such as ZEGFROVY® and DZD6008, both characterized by high target selectivity and favorable safety margins.

MIDD. As our pipeline products progress, we incorporate model-informed drug development ("**MIDD**") to seamlessly bridge preclinical insights with clinical performance. By integrating translational PK/PD and mechanistic data, we can accurately predict human PK, PD, and exposure response relationships. It supports precise dose selection, dosing-regimen optimization, and proactive safety evaluation, including drug-drug interaction assessment and special-population guidance. This approach also enhances trial design efficiency and overall program speed — exemplified by ZEGFROVY®, which completed dose escalation in only four cohorts and achieved market approval in under four years from first-patient-in. The following graphic sets forth the details of the MIDD framework.



In-house R&D Team

Our in-house R&D capabilities, built on our integrated platform, give us control and visibility over our R&D process, and enable us to ensure the quality and efficiency of our drug development programs.

As of September 30, 2025, our in-house R&D team consisted of 292 members, among whom 53.4% held master degrees and 19.5% held doctoral degrees, mainly in chemistry, biology, pharmacy, statistics and clinical medicine. Our creative and globally-oriented core management and R&D team leads and oversees all aspects of our drug development and commercialization efforts. Our core management team is composed of industry veterans with experiences from AstraZeneca, BMS, Eli Lilly, MSD, Pfizer, Roche, Sanofi, BeOne Medicines (formerly known as BeiGene), among others, and a proven track record of successful discovery, development and commercialization of innovative drugs.

R&D Process

Before initiating an R&D project, we conduct comprehensive market assessments to evaluate whether the potential product candidate addresses unmet medical needs and has sound commercial feasibility. We determine our R&D priorities by balancing clinical value and market prospects, having regard to potential market size, competition and likelihood of successful development.

At project initiation, we define key evaluation dimensions, including core, advantageous and non-core attributes, to ensure disciplined decision-making. Guided by our R&D logic of "identifying needs, elucidating mechanisms and achieving feasibility," we aim to develop drug candidates with clear target-disease mechanisms and practical clinical potential. Our R&D philosophy integrates translational science, clinical needs and market competition, allowing us to prioritize programs with high probability of success, meaningful differentiation and commercial potential.

The following summary highlights the key steps of our in-house R&D process for innovative drug development:

- ***Drug discovery and development.*** Before initiating a project, we adopt a clinically driven R&D approach to identify therapeutic targets addressing concrete and evolving clinical needs. We conduct in-depth research into disease mechanisms, foreseeable changes in the next five to ten years, and the development status of competing products. Once a clinical issue is clearly defined, our scientists propose potential targets and testable scientific hypotheses based on existing knowledge and research experience. Guided by these hypotheses, we design and perform a series of experiments across protein, cellular and animal levels to validate or refine the target-disease relationship, which represents one of our core research capabilities. Upon project establishment, our R&D team designs targeted experiments for each research stage, conducts high-throughput screening of thousands to millions of compounds, and identifies and optimizes lead compounds. Through iterative optimization, we select two to three promising candidates with differentiated characteristics, during which relevant biomarkers are validated and refined.

- ***Preclinical studies.*** Our preclinical development comprises a series of studies on candidate compounds, including pharmacodynamic, pharmacokinetic, safety pharmacology, toxicology, and chemistry, manufacturing and controls ("**CMC**") studies. These studies are designed to comprehensively assess the pharmacological activity, pharmacokinetic profile, and safety characteristics of candidate compounds.

  We also take into account the specific requirements of the jurisdictions where our Phase 1 clinical trials will be conducted and complete the corresponding studies in compliance with applicable regulatory standards. All toxicology studies are carried out in accordance with Good Laboratory Practice ("**GLP**") requirements.

- ***IND application.*** At the IND application stage, we prepare and compile the required documentation in accordance with the regulatory requirements of the relevant jurisdictions, and submit applications for approval to initiate clinical trials for our investigational new drugs.

- ***Clinical development.*** Upon obtaining regulatory approval to initiate clinical trials, our investigational new drugs enter the clinical development stage, which generally consists of Phase 1, Phase 2 and Phase 3 clinical trials. Phase 1 clinical trials are early-stage studies primarily designed to evaluate pharmacology and human safety, focusing on tolerance and pharmacokinetics to support dosing regimen determination. Phase 2 clinical trials aim to explore the preliminary efficacy and safety of the drug in patients with the target indication and to inform trial design and dosing schemes for Phase 3 studies. Phase 3 clinical trials are confirmatory studies conducted to further verify the therapeutic efficacy and safety profile of the drug, assess the overall benefit-risk relationship, and provide key evidence for new drug registration applications. During clinical development, we conduct trials in full compliance with study protocols and Good Clinical Practice ("**GCP**") guidelines, and maintain close coordination with clinical sites and investigators to ensure data accuracy and timely progress.

- ***NDA submission and approval.*** Upon completion of clinical trials, if the results meet expectations and the safety and efficacy of the drug are confirmed, and the manufacturing conditions comply with relevant GMP requirements, we submit a New Drug Application ("**NDA**") to the competent regulatory authorities for marketing approval. The new drug may be commercially launched after obtaining such approval.

- ***Post-marketing studies.*** After the marketing approval of a new drug, we may conduct post-marketing studies to evaluate its efficacy and adverse reactions under broader real-world usage conditions. Such studies aim to assess the benefit-risk profile in general or specific populations and to explore potential improvements in dosing regimens. Post-marketing studies are primarily conducted on a voluntary basis and may cover Phase 4 clinical studies, post-marketing surveillance and re-evaluation, or other research required or recommended by regulatory authorities.

For further details about the laws and regulations related to the registration o pharmaceutical products in China, see "Regulatory Overview — Overview of Laws and Regulations in the PRC — Laws and Regulations in Relation to New Drugs.

Collaboration with CROs

As a supplement to our in-house clinical capabilities, we also collaborate with reputable CROs worldwide to manage, conduct, and support our clinical trials. The services they provide under our supervision include site management, patient recruitment and data management for our clinical trials, as well as preclinical and clinical laboratory testing and other specialized tasks aligned with our needs.

We engage CROs based on a comprehensive evaluation of multiple criteria, including their technical capabilities, relevant therapeutic area expertise, track record of service excellence, operational efficiency, market standing, their long-term relationship with us and cost-effectiveness. We execute tailored service agreements with our CROs on a project-specific basis, which set forth the precise scope of services, operational procedures, expected deliverables, project milestones, and payment arrangements. We maintain rigorous oversight of our CRO partners to ensure their activities align with our study protocols, meet all regulatory standards, and comply with applicable legal requirements, thereby safeguarding the quality and reliability of data generated from our clinical trials and studies.

Below is a summary of the key terms of a typical agreement we enter with our CROs:

- ***Services.*** In line with industry practice, CROs support us in matters such as trial management and compliance with regulatory requirements.

- ***Term.*** The CROs are required to perform their services within the prescribed time limit set out in each work order.

- ***Payments.*** We are required to make payments to the CROs in accordance with a payment schedule agreed by the parties.

- ***Intellectual property rights.*** All clinical results, reports, publications, and related rights and interests, including all intellectual property rights in connection with the performance of the agreements, are owned by us.

- ***Confidentiality.*** The CRO is required to keep confidential all the data, information or contents we distributed to them related to the project specified in the agreement, and such obligation may survive the termination of the cooperation agreement.

MANUFACTURING

We have historically engaged, and will continue to engage, industry-recognized CDMOs for certain aspects of our commercial production and clinical manufacturing.

We selected our CDMO partners after thoroughly evaluating factors such as manufacturing capacity and qualifications, service and product quality, reputation, costs, and alignment with our R&D objectives. To monitor and evaluate the partner's performance, we have implemented internal controls to ensure full compliance with applicable regulatory requirements and our internal quality management system. Our agreement with CDMOs specify detailed manufacturing procedures and requirements to ensure compliance with our stringent quality standards. Below is a summary of the key terms of a typical agreement we enter with our CDMO partners:

- ***Services.*** Production of active pharmaceutical ingredients, drug candidates or drugs as specified in the master agreement or a work order.

- ***Term.*** The term of our agreement with the CDMOs is generally three to five years. The CDMOs are required to perform their services prescribed timeframe set out in the master agreement or a work order.

- ***Payments.*** We are required to make payments to the CDMOs in accordance with the payments schedule set forth in the agreement, which is typically linked to the stages of the manufacturing process and the deliverables we receive.

- ***Intellectual properties.*** We own all intellectual property rights relating to our products arising from the outsourced manufacturing processes.

For risks relating to our relationship with CDMOs, see "Risk Factors — Risks Relating to Dependence on Third Parties — We rely on third parties to conduct the manufacturing of our marketed products and drug candidates during the Track Record Period, and any disruption, quality issue or capacity constraint at such third parties could adversely affect our business, financial condition and results of operations."

To enhance production efficiency, strengthen quality control and optimize cost structure, we are transitioning toward in-house manufacturing. Through vertical integration, we aim to achieve refined control and improved efficiency across the production process, and capture economies of scale as our commercial products expand. We expect this transition to enable us to align manufacturing planning more closely with R&D and commercialization needs, accelerate the scale-up of future products, and enhance overall capital utilization efficiency.

In line with this strategy, we have completed the construction of our manufacturing facility in Wuxi, Jiangsu in October 2025, which is designed to meet GMP requirements of China and the United States and has an annual capacity of approximately 70 million tablets and 20 million capsules. The facility obtained the Drug Manufacturing License in December 2025,

with process transfer and validation to follow, and commercial production targeted to begin in 2027. The Wuxi facility will enable us to form a fully integrated industrial chain covering preclinical research, clinical development and commercial-scale manufacturing, supporting growing domestic and international demand while establishing a cost-competitive and scalable production foundation for future commercialization. The synergies between our R&D and manufacturing teams will further drive process innovation, cost competitiveness and sustainable profitability.

The following table sets forth a summary of our manufacturing facility in Wuxi.

Facility Location	Site area	GFA	Major products to be produced	Production capacity[(1)]
	(sq.m.)	*(sq.m.)*		
Wuxi, Jiangsu province	62,234.2	37,739	Our small-molecule innovative drugs including ZEGFROVY®, golidocitinib and other drug candidates	70 million tablets and 20 million capsules

Note:

(1) The production capacity of our production line is calculated based on 250 effective working days per year on a single-shift basis (i.e. 8 hours per day).

QUALITY MANAGEMENT

We believe that a robust quality management system is fundamental to ensuring the safety, efficacy and quality consistency of our products. Our quality system has been established in accordance with the ICH Q10 Pharmaceutical Quality System model and other applicable ICH guidelines, including ICH Q8 and Q9, as well as the NMPA regulatory requirements under the Marketing Authorization Holder ("**MAH**") regime. Our quality system also complies with the applicable laws, regulations and industry standards, including but not limited to the Drug Administration Law, Good Manufacturing Practice ("**GMP**"), Good Supply Practice ("**GSP**") and Good Pharmacovigilance Practice ("**GVP**"), and is continuously upgraded in line with the latest regulatory developments. Our quality framework covers a broad spectrum of areas including quality management system, organization and personnel, infrastructure, data and documentation, audits and inspections, outsourced activities, supplies and materials management, complaints and product recall, processes and controls, qualification and validation, and quality control. Necessary supervisions are implemented throughout the product life cycle, and, coupled with knowledge management and risk management, facilitate science- and risk-based decision-making related to product quality.

We have established a Quality Department with over 30 professionals for MAH and site quality management as of September 30, 2025. The department oversees the operation of the quality system across R&D, manufacturing, testing, storage and distribution, ensuring adherence to GMP, GSP and GVP regulations, as well as the GCP requirements in clinical trial phase. It is responsible for drafting, revising and reviewing quality documents and reports, approving or rejecting raw materials and finished products, investigating deviations, monitoring suppliers and contractors, and maintaining data integrity. The regular internal audit is required and conducted to ensure effective operation of the quality system and its continuous improvements. The authorized quality person is responsible for the final release of MAH products, ensuring that all of our products on the market meet the approved quality standards.

Key aspects of our quality control and assurance procedures are as follows:

Procurement of Raw Materials and Quality Control

Raw materials are procured from approved suppliers in accordance with internal quality management procedures. Upon receipt, warehousing personnel inspect the materials and associated documents to ensure accuracy and integrity. All raw materials are kept in quarantine until release testing has been completed. The Quality Control ("**QC**") team conducts sampling and release testing on each incoming batch to confirm compliance with established specifications. Only materials that have successfully passed release testing and obtained approval from Quality Assurance ("**QA**") team can be used in production. Full traceability is maintained throughout the entire material management process in compliance with GMP requirements.

Product In-process Quality Control

Applicable procedures have been established to ensure continuous compliance of manufacturing operations with GMP requirements and internal standard operating procedures. Production staff are required to strictly follow validated and/or qualified process parameters, operating instructions and equipment specifications. Meanwhile, Quality Department conducts routine on-site inspections to monitor process performance and data integrity. Upon completion of each production stage, thorough equipment cleaning and line clearance of the production area are carried out to prevent contamination or cross-contamination.

Finished Product Quality Control

In accordance with the product release procedures, each batch of finished products is subject to sampling and release testing, with corresponding testing reports issued. All quality-related documentation, including batch production records, testing records, and any deviations or changes, is reviewed by QA team in line with the release procedures. This ensures that products released for distribution have been manufactured and tested in compliance with applicable regulations, product registration requirements, and relevant specifications. The Quality Department is responsible for reviewing and approving product release for distribution or market entry, thereby ensuring the effective implementation of the quality system and maintaining oversight of product quality throughout the entire product lifecycle. Any products failing to meet release standards will be handled and disposed of in accordance with quality management procedures.

Inventory Management

Our inventories primarily consist of raw materials, work in progress and finished products. We have established a comprehensive inventory management system to ensure accurate, traceable and compliant management of materials and finished goods across procurement, warehousing and production. Each relevant department prepares and updates demand and procurement plans based on market conditions and production needs to maintain appropriate inventory levels. We conduct regular and ad hoc inventory counts and system reconciliations to ensure consistency between physical stock and system records. Any identified discrepancies are investigated and adjusted through documented approval procedures. Our QA team oversees warehouse management and storage conditions in compliance with GMP requirements, while our Finance Department reviews and audits inventory records on a periodic basis. We utilize an SAP-based digital management system for inventory tracking and reconciliation, enabling full traceability and enhancing the efficiency and integrity of our inventory management.

COMMERCIALIZATION STRATEGIES AND SALES MODEL

Our Commercialization Team

We have established a proven nationwide commercialization system with a structured organizational framework and clear functional divisions, enabling efficient coordination and the smooth execution of marketing activities. Our high-caliber commercialization team has been strategically curated into integration functions, including marketing, clinical promotion, market access, medical affairs, commercial channels, and business planning and operations, to effectively promote the clinical benefits of our products and enhance our sales productivity. As of September 30, 2025, our integrated commercialization team comprised 592 seasoned professionals who have extensive expertise in the sales and marketing of pharmaceutical goods. In particular, most of them have deep commercialization experience in lung cancer and hematologic oncology, further enabling the specialized academic promotion of our products.

We adhere to a commercialization strategy of proactive pre-launch planning and a comprehensive post-launch commercialization approach to accelerate the realization of product value. As our drug candidates approach regulatory approval, we initiate systematic commercialization preparation centered on clear market positioning strategy, professional training, comprehensive hospital mapping, evidence support for clinical guideline inclusion, nationwide marketing network expansion, and optimization of market access pathways. As an example of our market access capabilities, golidocitinib achieved same-year NRDL inclusion following its approval, allowing expedient patient access post-launch. Looking ahead, we plan to expand our commercialization capabilities beyond China through diversified cooperation models with leading international pharmaceutical companies, while exploring the appropriate timing to establish a lean in-house global commercialization team. This strategic approach allows us to deliver the clinical value of our products precisely to medical demand, replicate past commercialization success, and strengthen our foundation for sustainable global growth. For additional information regarding our business sustainability and path to profitability, see "Financial Information — Liquidity and Capital Resources — Path to Profitability."

Our Distribution Model

During the Track Record Period, we generated revenue from sales of our marketed products, namely ZEGFROVY® and golidocitinib through distributorship, in China.

We enter into annual distribution agreements with a number of distributors, which are pharmaceutical enterprises legally established under the laws of the PRC. Pursuant to such agreements, we sell our products to the distributors, who are responsible for allocation and delivery of the products to hospitals or pharmacies within their respective authorized territories. Ownership of, and the risk of loss relating to, the products are fully transferred to the distributors upon delivery by the company. Distributors are not entitled to return or exchange the products for any reason, save for cases involving product defects.

To the best knowledge of our Directors, all our distributors during the Track Record Period and up to the Latest Practicable Date were Independent Third Parties. None of the distributors who transacted with us during the Track Record Period and up to the Latest Practicable Date were controlled by our former or current employees, uses our brand or name (except where expressly authorized by us for specific promotional activities), or has received any material advance or financial assistance from us.

Distributor Network

As of September 30, 2025, our distributor network comprised 38 distributors across China.

The following table sets forth the movement of the number of our distributors for the years/periods indicated.

	For the year ended December 31,		For the nine months ended September 30,
	2023	**2024**	**2025**
Number of distributors at the beginning of the year/period[(1)]	–	25	30
Addition of new distributors[(2)]	25	5	9
Termination of existing distributors[(3)]	–	–	(1)
Net increase/(decrease) in distributors	25	5	8
Number of distributors at the end of the year/period	25	30	38

Notes:

(1) The numbers of distributors in this table are calculated on entity level, without combining distributors belonging to the same group.

(2) New distributors refer to distributors who (i) had at least one transaction with us in the relevant period; and (ii) did not have any transaction with us in the immediately preceding financial year.

(3) Terminated distributors refer to distributors who (i) did not have any transaction with us in the relevant period; and (ii) had at least one transaction with us in the immediately preceding financial year. We terminated one distributor in the nine months ended September 30, 2025, as we continued to optimize our distribution network by engaging distributors that are better suited to the regional market conditions and our business needs.

Distributor Management

When selecting our distributors, we conduct comprehensive qualification and business assessments. We evaluate their operational scale, distribution capabilities, financial stability, commercial reputation, and integrity. Our distributors are also required to maintain professional logistics personnel and adequate transportation and management resources to ensure the safe and compliant delivery of our products. A prerequisite for engaging any distributor is that it must be a pharmaceutical enterprise legally established under the laws of the PRC. We have also established a formal review process to regularly assess our distributors' performance.

Terms of Distribution Agreements

We enter into annual distribution agreements with our distributors. Individual sales contracts or purchase orders are generally entered into or placed for each purchase separately. The following sets forth salient terms of our framework distribution agreements:

- ***Term.*** The typical duration of annual distribution agreements is one year.

- ***Designated distribution area.*** Distributors are generally not allowed to sell our products outside of their designated distribution areas.

- ***Exclusivity.*** Distributors are granted the distributorship right for specified types of products in their designated areas.

- ***Sales target and minimum purchase requirement.*** Our agreements with distributors generally do not specify a mandatory annual sales target or minimum annual purchase amount.

- ***Pricing.*** Our selling prices to distributors are generally fixed during the term of the distribution agreements. In the event of changes in market conditions during the term of the distribution agreements, we typically negotiate with our distributors to make corresponding price adjustments.

- ***Product return and exchange.*** Our distributors may perform product acceptance upon delivery. Returns and exchanges are not allowed without our prior written consent unless in cases of product defects.

- ***Credit terms.*** We typically grant our distributors a credit term of around 60 days.

- ***Termination.*** We may terminate the distribution agreements in the event of, among others, any material breach by our distributors of the agreement or at our discretion any time by giving prior written notice to the distributors.

- ***Compliance.*** Our distributors are required to comply with PRC laws and regulations, including anti-corruption and anti-bribery laws and regulations.

Prevention of Channel Stuffing

We have implemented a series of measures to prevent channel stuffing and ensure that our product distribution remains aligned with genuine market demand:

- ***Inventory management.*** We have established assessment mechanisms under which distributors' inventory management performance forms part of their overall evaluation. Distributors are encouraged to maintain rational inventory levels that support stable supply without accumulation of excess stock. We regularly obtain the distributors' inventory levels to ensure that month-end stock remains within a reasonable range, taking into account factors such as product sales cycles and the growth trajectory of newly launched products.

- ***Sales data reporting and monitoring.*** Our distributors are required to provide reports on product sales and inventory data normally on a monthly basis. We review such information to identify abnormal stock movements and take timely actions to mitigate potential distribution risks.

During the Track Record Period and up to the Latest Practicable Date, we did not identify any unusual procurements or sales activities that were inconsistent with distributors' past practices, or any abnormally high inventory level of our distributors.

Prevention of Cannibalization

To mitigate the risk of sales cannibalization within our domestic distribution network, we have implemented a series of measures. Particularly, our distributors are designated by region, and each distributor is responsible for sales within its assigned geographic region. This regional allocation minimizes overlap and ensures a clear delineation of distribution responsibilities. Under our distribution agreements, each primary distributor is expressly prohibited from directly or indirectly engaging in any sales or shipments outside its designated territory, or conducting any activities that breach the terms of the agreement or infringe upon the interests of other third parties. Distributors are not permitted to conduct sales outside their designated areas without prior approval from us.

Our Directors are of the view that the above measures are effective to mitigate potential cannibalization and competition among our domestic distributors. During the Track Record Period and up to the Latest Practicable Date, we had not identified any material instances of cannibalization or malicious competition among our domestic distributors.

Implication of and Compliance with the "Two-Invoice System" in China

Our marketed products are subject to the "Two-Invoice System" in China, a pharmaceutical procurement policy designed and enforced by the PRC government to reduce drug prices by streamlining the supply chain. Under this system, only two invoices are allowed between manufacturers and hospitals or other medical institutions: one from the manufacturer to the distributor, and another from the distributor to the hospitals (or other medical institutions). This system, which is mandatory for public medical institutions, and its adoption is encouraged but not mandatory for other medical institutions, reduces potential markups by multiple layers of distributors, promoting pricing transparency. Manufacturers and distributors that violate the two-invoice system requirements may face disqualification from future public tenders, loss of hospital distribution rights, and inclusion on procurement blacklists. For details, see "Regulatory Overview — Overview of Laws and Regulations in the PRC — Other Laws and Regulations in Relation to Medical Industry — Drug Distribution and Two-Invoice System." In the cases that the end-customers are non-medical institutions or pharmacies, we do not prohibit our distributors from engaging sub-distributors, as such sales are not subject to the mandatory requirements of two-invoice system. We do not have contractual relationships with any sub-distributors engaged by our distributors, and our distributors are primarily responsible for monitoring the performance of the sub-distributors they engage. Our commercialized products are distributed to medical institutions in China in compliance with the Two-Invoice System requirements.

Marketing Activities

We begin comprehensive commercialization planning approximately 18 to 24 months before the anticipated approval of each product candidate. Our preparations include developing internal strategy of product positioning and differentiation, building internal marketing and compliance systems, establishing supply chain readiness, and developing market access and reimbursement pathways. During this stage, we also identify and engage KOLs and major hospitals through scientific exchanges to increase awareness of evolving treatment paradigms and facilitate evidence generation and potential future inclusion in relevant treatment guidelines.

Following the product approval, we organize, sponsor and participate in academic conferences, seminars and symposia, sharing the latest clinical data and therapeutic insights. Our medical team facilitates scientific dialogues, while our commercialization team maintain regular communication with healthcare professionals to convey regulatory approved information on product use, safety and efficacy, and to collect feedback from clinical practice. Such interactions help us gain valuable clinical and market insights and continuously refine our commercialization strategies to better meet patient and medical needs.

PRICING

During the Track Record Period, all of our revenue generated from the sales of our pharmaceutical products was derived from China. Our pricing strategies are affected by the regulatory framework governing pharmaceutical reimbursement in China, which operates through multiple interconnected mechanisms that collectively determine both market access opportunities and pricing parameters for pharmaceutical products in China's public healthcare system. The regulatory regimes that directly impact our pricing and market access primarily include the NRDL governing insurance coverage and reimbursement standards. We continuously monitor regulatory developments and adapt our pricing strategies to navigate these complex mechanisms while maintaining sustainable business operations.

NRDL

The NRDL forms the basis for medical insurance coverage and reimbursement standards under China's basic medical insurance, work-related injury insurance and maternity insurance programs. NRDL inclusion significantly influences market dynamics by determining patient access to insurance reimbursement for covered medications, thereby affecting both demand patterns and achievable pricing levels. The NHSA, in conjunction with other relevant government authorities, maintains authority over NRDL composition and updates the list through rigorous evaluation processes that assess clinical necessity, cost-effectiveness and budgetary impact. Products undergo comprehensive evaluation based on established selection criteria including clinical efficacy, safety profiles, therapeutic value compared to existing alternatives, and economic considerations.

As of September 30, 2025, our marketed products ZEGFROVY® and golidocitinib were included in the NRDL. See also "— Our Product Portfolio." NRDL inclusion represents both an opportunity for enhanced market access and a commitment to pricing frameworks that support broad patient accessibility within China's healthcare insurance system. While NRDL inclusion provides substantial market advantages through enhanced patient accessibility and reduced out-of-pocket costs, it may also result in price adjustments through negotiated pricing mechanisms designed to balance patient access with healthcare system sustainability.

For further details on the risks associated with the pricing regulations in China, as well as the NRDL and other government-sponsored medical insurance programs, see "Risk Factors — Risks Relating to Our Business and Industry — If our products fail to be timely included in, or are removed or excluded from, national, provincial or other government-sponsored medical insurance programs, our revenue and financial performance could be adversely affected."

OUR CUSTOMERS

During the Track Record Period, our customers were our distributors who purchase drug products from us, allocate within designated regions or resell to end-customers. Our revenue from our five largest customers for each year/period during the Track Record Period amounted to RMB82.9 million, RMB322.3 million and RMB478.2 million, respectively, accounting for 90.8%, 89.6% and 81.7% of our total revenue, respectively. Our revenue from our largest customer for each year/period during the Track Record Period amounted to RMB35.9 million, RMB139.6 million and RMB239.5 million, respectively, accounting for 39.3%, 38.8% and 40.9% of our total revenue, respectively. For details of the risks related to our major customers, see "Risk Factors — Risks Relating to Dependence on Third Parties — The potential loss of major customers or any of our large contracts could materially affect our business, financial condition and results of operations."

The following table sets forth details of our five largest customers for each year/period during the Track Record Period:

Customer	Background	Products Provided	Credit Terms	Commencement of Business Relationship (Since)	Revenue Contribution	% of Total Revenue for the Period/Year
					(RMB in thousands)	*(%)*
For the nine months ended September 30, 2025						
Customer Group A	A leading state-owned pharmaceutical company group headquartered in China	Pharmaceutical products	60 days	2023	239,507	40.9
Customer Group B	A leading state-owned pharmaceutical company group headquartered in China listed on the Hong Kong Stock Exchange and the Shanghai Stock Exchange	Pharmaceutical products	60 days	2023	87,414	14.9
Customer Group C	A leading state-owned pharmaceutical company group headquartered in China	Pharmaceutical products	60 days	2023	67,829	11.6
Customer Group D	A leading state-owned pharmaceutical company group headquartered in China listed on the Shanghai Stock Exchange	Pharmaceutical products	60 days	2023	45,494	7.8
Customer E	A leading state-owned pharmaceutical company headquartered in China	Pharmaceutical products	60 days	2023	37,908	6.5
Total					**478,152**	**81.7**

Customer	Background	Products Provided	Credit Terms	Commencement of Business Relationship (Since)	Revenue Contribution	% of Total Revenue for the Period/Year
					(RMB in thousands)	*(%)*
For the year ended December 31, 2024						
Customer Group A	A leading state-owned pharmaceutical company group headquartered in China	Pharmaceutical products	60 days	2023	139,589	38.8
Customer Group B	A leading state-owned pharmaceutical company group headquartered in China listed on the Hong Kong Stock Exchange and the Shanghai Stock Exchange	Pharmaceutical products	60 days	2023	80,313	22.3
Customer Group C	A leading state-owned pharmaceutical company group headquartered in China	Pharmaceutical products	60 days	2023	40,250	11.2
Customer Group D	A leading state-owned pharmaceutical company group headquartered in China listed on the Shanghai Stock Exchange	Pharmaceutical products	60 days	2023	33,688	9.4
Customer E . . .	A leading state-owned pharmaceutical company headquartered in China	Pharmaceutical products	60 days	2023	28,441	7.9
Total					**322,281**	**89.6**

Customer	Background	Products Provided	Credit Terms	Commencement of Business Relationship (Since)	Revenue Contribution	% of Total Revenue for the Period/Year
					(RMB in thousands)	*(%)*
For the year ended December 31, 2023						
Customer Group A	A leading state-owned biopharmaceutical company group headquartered in China	Pharmaceutical products	60 days	2023	35,861	39.3
Customer Group B	A leading state-owned pharmaceutical company group headquartered in China listed on the Hong Kong Stock Exchange and the Shanghai Stock Exchange	Pharmaceutical products	60 days	2023	20,088	22.0
Customer Group C	A leading state-owned pharmaceutical company group headquartered in China	Pharmaceutical products	60 days	2023	12,648	13.9
Customer Group D	A leading state-owned pharmaceutical company group headquartered in China listed on the Shanghai Stock Exchange	Pharmaceutical products	60 days	2023	8,779	9.6
Customer E . . .	A leading state-owned pharmaceutical company headquartered in China	Pharmaceutical products	60 days	2023	5,505	6.0
Total					**82,881**	**90.8**

To the best of our knowledge, (i) all of our five largest customers for each year/period during the Track Record Period were Independent Third Parties; and (ii) none of our Directors, their respective associates or any shareholder who owned more than 5% of our issued share capital of our Company as of the Latest Practicable Date, had any interest in any of our five largest customers for each year/period during the Track Record Period.

OUR SUPPLIERS

During the Track Record Period, our suppliers primarily consisted of suppliers of CRO services and CDMO services. We implement a strict procurement and supplier management system with comprehensive controls covering the entire procurement lifecycle. For details, see "— Quality Management — Procurement of Raw Materials and Quality Control."

Our purchases from our five largest suppliers for each year/period during the Track Record Period amounted to RMB301.9 million, RMB249.9 million and RMB243.8 million, respectively, accounting for 60.6%, 57.0% and 57.8% of our total purchases, respectively. Our purchases from the largest supplier for each year/period during the Track Record Period amounted to RMB127.0 million, RMB70.1 million and RMB79.0 million, respectively, accounting for 25.5%, 16.0% and 18.7% of our total purchases, respectively.

The following table sets forth details of our five largest suppliers for each year/period during the Track Record Period:

Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount	% of Total Purchases for the Period/Year
					(RMB in thousands)	*(%)*
For the nine months ended September 30, 2025						
Supplier A	A private company established in China, a subsidiary of a pharmaceutical group listed on the NASDAQ Exchange headquartered in the United States, primarily engages in pharmaceutical R&D-related technical services and clinical trial support	R&D services	45 to 90 days	2019	78,959	18.7
Supplier B	A private company headquartered in the United States, primarily engages in clinical trial management, pharmaceutical R&D outsourcing and related technical services	R&D services	30 days	2022	49,474	11.7

Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount	% of Total Purchases for the Period/Year
					(RMB in thousands)	*(%)*
Supplier Group C	A public company group listed on the New York Stock Exchange headquartered in the United States, primarily engages in R&D, production and sales of scientific instruments, reagents, lab consumables, and life science and pharmaceutical R&D-related technical services	R&D services and materials	45 to 60 days	2018	47,587	11.3
Supplier Group D	A public company group listed on the Shanghai Stock Exchange headquartered in China, primarily engages in pharmaceutical R&D outsourcing, new drug discovery, clinical trials and production-related technical services	Manufacturing and R&D services	60 to 90 days	2018	47,495	11.3
Supplier Group E	A private company group headquartered in the United States, primarily engages in pharmaceutical R&D outsourcing, clinical trial management, pharmaceutical commercial consulting and related technical services	R&D services	60 days	2019	20,241	4.8
Total					**243,756**	**57.8**

Note: We recognized U.S. FDA fees of RMB31.0 million in connection with the NDA approval of ZEGFROVY® during the nine months ended September 30, 2025.

Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount	% of Total Purchases for the Period/Year
					(RMB in thousands)	*(%)*
For the year ended December 31, 2024						
Supplier Group C	A public company group listed on the New York Stock Exchange headquartered in the United States, primarily engages in R&D, production and sales of scientific instruments, reagents, lab consumables, and life science and pharmaceutical R&D-related technical services	R&D services and materials	45 to 60 days	2018	70,137	16.0
Supplier Group D	A public company group listed on the Shanghai Stock Exchange headquartered in China, primarily engages in pharmaceutical R&D outsourcing, new drug discovery, clinical trials and production-related technical services	Manufacturing and R&D services	60 to 90 days	2018	60,102	13.7
Supplier B	A private company headquartered in the United States, primarily engages in clinical trial management, pharmaceutical R&D outsourcing and related technical services	R&D services	30 days	2022	58,615	13.4

Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount	% of Total Purchases for the Period/Year
					(RMB in thousands)	*(%)*
Supplier A	A private company established China, a subsidiary of a pharmaceutical group listed on the NASDAQ Exchange headquartered in the United States, primarily engages in pharmaceutical R&D-related technical services and clinical trial support	R&D services	45 to 90 days	2019	32,201	7.3
Supplier Group E	A private company group headquartered in the United States, primarily engages in pharmaceutical R&D outsourcing, clinical trial management, pharmaceutical commercial consulting and related technical services	R&D services	60 days	2019	28,845	6.6
Total					**249,900**	**57.0**

Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount	% of Total Purchases for the Period/Year
					(RMB in thousands)	*(%)*
For the year ended December 31, 2023						
Supplier Group F	A public company group headquartered in the U.S., primarily engaged in medical testing, clinical research support and pharmaceutical R&D-related laboratory services.	R&D services and materials	60 to 90 days	2019	126,996	25.5
Supplier Group D	A public company group listed on the Shanghai Stock Exchange headquartered in China, primarily engages in pharmaceutical R&D outsourcing, new drug discovery, clinical trials and production-related technical services	Manufacturing and R&D services	60 to 90 days	2018	67,547	13.5
Supplier B	A private company headquartered in the United States, primarily engages in clinical trial management, pharmaceutical R&D outsourcing and related technical services	R&D services	30 days	2022	41,363	8.3

Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount	% of Total Purchases for the Period/Year
					(RMB in thousands)	*(%)*
Supplier Group C	A public company group listed on the New York Stock Exchange headquartered in the United States, primarily engages in R&D, production and sales of scientific instruments, reagents, lab consumables, and life science and pharmaceutical R&D-related technical services	R&D services and materials	45 to 60 days	2018	39,129	7.9
Supplier Group E	A private company group headquartered in the United States, primarily engages in pharmaceutical R&D outsourcing, clinical trial management, pharmaceutical commercial consulting and related technical services	R&D services	60 days	2019	26,881	5.4
Total					**301,916**	**60.6**

To the best of our knowledge, (i) all of our five largest suppliers for each year/period during the Track Record Period were Independent Third Parties; (ii) none of our Directors, their respective associates or any shareholder who owned more than 5% of our issued share capital of our Company as of the Latest Practicable Date, had any interest in any of our five largest suppliers for each year/period during the Track Record Period.

OVERLAPPING OF OUR MAJOR SUPPLIERS AND CUSTOMERS

Two of our five largest customers during each period of the Track Record Period, namely Customer Group A and Customer Group B, were also the parent companies of certain of our suppliers. Our sales to Customer Group A amounted to RMB35.9 million, RMB139.6 million and RMB239.5 million in 2023, 2024 and the nine months ended September 30, 2025, respectively, accounting for approximately 39.3%, 38.8% and 40.9% of our total revenue for the respective years/period. Our sales to Customer Group B amounted to RMB20.1 million, RMB80.3 million and RMB87.4 million in 2023, 2024 and the nine months ended September 30, 2025, respectively, accounting for approximately 22.0%, 22.3% and 14.9% of our total revenue for the respective years/period.

During the Track Record Period, we procured warehousing and logistics services, as well as R&D laboratory consumables and related materials, from Customer Group A. Our purchases from Customer Group A amounted to approximately RMB0.02 million, RMB0.6 million and RMB1.4 million in 2023, 2024 and the nine months ended September 30, 2025, accounting for approximately nil, 0.1% and 0.3% of our total purchases in the respective periods.

During the Track Record Period, we also procured warehousing and logistics services from Customer Group B. Our purchases from Customer Group B amounted to approximately RMB0.5 million, RMB0.6 million and nil in 2023, 2024 and the nine months ended September 30, 2025, accounting for approximately 0.1%, 0.1% and nil of our total purchases in the respective periods.

While the counterparties to us for the sales and purchases above were separate legal entities with distinct business operations, they are under common ultimate control within the same group, which has an extensive presence in pharmaceutical distribution and related services in the PRC. Our Directors confirm that the pricing and transaction terms of our sales to Customer Group A and Customer Group B, as well as our purchases from their groups' supplier entities were negotiated and conducted separately on an arm's length basis and in the ordinary course of business. Such transactions were neither connected with nor conditional upon each other, and the transaction terms (including payment schedules, credit periods and pricing) were consistent with those offered to independent third parties of similar nature.

Save as disclosed above, none of our five largest customers in each period during the Track Record Period were also our suppliers during the same period, and vice versa.

PRODUCT RETURNS AND WARRANTIES

Product returns or exchanges by our distributors are generally not permitted except under circumstances defined in our internal Returned Products Management Standard Operating Procedure ("**SOP**"). In accordance with our SOP and the Good Supply Practice for Drugs (《藥品經營質量管理規範》) of the PRC, all distributors are required to conduct acceptance inspections upon delivery to ensure that only qualified products enter their inventory.

Our return management process distinguishes between returns due to quality-related reasons and those for non-quality reasons, each governed by dedicated approval and handling procedures. Returns for quality reasons may include potential product quality issues, packaging damage identified upon receipt, or temperature excursions during transportation. Non-quality reasons may include logistics errors, near-expiry products, or other market-related causes. All return applications must be submitted through our distribution management system and undergo step-by-step review and approval by Commercial Operations and QA. QA is responsible for assessing returned products, supervising their handling — including repackaging, destruction or resale where appropriate — and ensuring that all actions are fully documented and traceable in accordance with our SOP.

In addition, we have established a dedicated quality complaint-handling mechanism. Our quality personnel receive, log and investigate feedback from distributors and healthcare professionals, and work closely with Commercial Operations to evaluate the nature of any reported quality issue. Approved product returns are coordinated with distributors for collection, transportation and subsequent inspection under QA supervision. During the Track Record Period and up to the Latest Practicable Date, we had not received any material customer complaints due to problems associated with the quality of our products or encountered any material product returns for quality reasons.

INTELLECTUAL PROPERTY

Intellectual property rights are crucial to our business success. Our future success is highly dependent on our ability to obtain and maintain robust patent protection, as well as other forms of intellectual property rights, in respect of the key technologies, inventions and proprietary know-how underpinning our product pipeline and technology platform. Equally critical is our ability to maintain and enforce these intellectual property rights, preserve the confidentiality of our trade secrets, and ensure our freedom to operate without infringing on, misappropriating or otherwise violating the valid intellectual property rights of third parties.

We hold a global portfolio of patents to protect our product portfolio and technologies. As of the Latest Practicable Date, we owned 176 issued patents, including 32 in China, 19 in the U.S., and 125 in other jurisdictions. As of the same date, we had 198 patent applications, including 14 in China, 13 in the U.S., 168 in other jurisdictions and three under the Patent Cooperation Treaty ("**PCT**") filed in China. As of the Latest Practicable Date, we had not received any material concerns or inquiries from relevant competent authorities that make us believe that any of the pending patent applications will be rejected. The following table sets forth an overview details of the granted patents and patent applications for marketed products and product candidates that are material to our business operations as of the Latest Practicable Date. For details of our intellectual properties, see Appendix VI to this document.

Related Product	Scope of Patent Protection	Category	Grant No./ Application No.	Jurisdiction	Status	Patent Holders/ Applicants	Expiration Date[1]
ZEGFROVY®	Compounds of ErbB/PTK Inhibitors	Invention	CN111909131B	China	Granted	Our Company	January 28, 2039
	Compounds of ErbB/PTK Inhibitors	Invention	US11007198B2	United States	Granted	Our Company	January 28, 2039
	Compounds of ErbB/PTK Inhibitors	Invention	US11504375B2	United States	Granted	Our Company	January 28, 2039
	Compounds of ErbB/PTK Inhibitors	Invention	US11896597B2	United States	Granted	Our Company	January 28, 2039
Golidocitinib	Compounds and Methods for Inhibiting JAK	Invention	CN108368091B	China	Granted	Our Company	September 22, 2036
	Compounds and Methods for Inhibiting JAK	Invention	CN111606893B	China	Granted	Our Company	September 22, 2036
	Compounds and Methods for Inhibiting JAK	Invention	CN111646980B	China	Granted	Our Company	September 22, 2036
	Compounds and Methods for Inhibiting JAK	Invention	CN111848586B	China	Granted	Our Company	September 22, 2036
	Compounds and Methods for Inhibiting JAK	Invention	US9714236B2	United States	Granted	Our Company	September 22, 2036
	Compounds and Methods for Inhibiting JAK	Invention	US10167276B2	United States	Granted	Our Company	September 22, 2036
	Compounds and Methods for Inhibiting JAK	Invention	US10654835B2	United States	Granted	Our Company	September 22, 2036

Related Product	Scope of Patent Protection	Category	Grant No./ Application No.	Jurisdiction	Status	Patent Holders/ Applicants	Expiration Date[1]
	Compounds and Methods for Inhibiting JAK	Invention	US11247983B2	United States	Granted	Our Company	September 22, 2036
	Compounds and Methods for Inhibiting JAK	Invention	US12319670B2	United States	Granted	Our Company	September 22, 2036
Birelentinib . . .	Compounds of BTK Inhibitors	Invention	CN114945574B	China	Granted	Our Company	December 29, 2040
DZD6008	Compounds and uses of EGFR inhibitors	Invention	CN202380062433.7	China	Pending	Our Company	N/A
	Compounds and uses of EGFR inhibitors	Invention	US19/107192	United States	Pending	Our Company	N/A

Note:

(1) The patent expiration date is estimated based on current filing status, without considering any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

COMPETITION

The pharmaceutical industry is defined by fast-evolving technologies, intense competition, and a significant focus on proprietary drug development. Although our robust drug portfolios, advanced R&D expertise, integrated technology platform, and experienced management team give us a competitive advantage, we encounter competition from diverse sources, including large domestic and international pharmaceutical companies, as well as smaller emerging pharmaceutical companies, who may currently market and sell products or are pursuing the development of drug candidates for the treatment of the same indications as our products and drug candidates. For details of the competitive dynamics and the relevant risks, see "Risk Factors — Risks Related to Our Business and Industry — We operate in a highly competitive environment, and we may not be able to compete effectively against current and future competitors, which could adversely affect our financial performance."

Our strategy focuses on advancing our approved drugs and clinical-stage assets through key development milestones and to continue exploring new targets, expanded indications and combination regimens in oncology and immunology diseases. In addition, we plan to strengthen our core technological competencies, while continuously enhancing commercialization capabilities to realize the full market potential of our pipeline. We aim to expand global partnerships to unlock the commercial value of our approved and pipeline products. In parallel, we plan to strengthen in-house manufacturing to support scalable supply and improve cost efficiency. Underpinning these efforts, we prioritize attracting, developing, and retaining top-tier talent across R&D, manufacturing, and commercialization to support long-term growth and global expansion.

EMPLOYEES

As of September 30, 2025, we had 997 full-time employees, all of whom were based in China. The following table sets forth the number of our employees by function as of September 30, 2025.

Functions	Number of employees	Percentage
Sales and Marketing	592	59%
Research and Development	292	29%
Manufacturing and Quality Management	45	5%
Finance	15	2%
General and Administration	53	5%
Total	**997**	**100.0%**

We believe we have maintained good relationships with our employees. Our employees do not negotiate their terms of employment through any labor union or by way of collective bargaining agreements. As of the Latest Practicable Date, we did not experience any strikes or any labor disputes with our employees which have had or are likely to have a material effect on our business.

As required by laws and regulations in China, we participate in various employee social security plans that are organized by municipal and provincial governments including, among other things, pensions, medical insurance, unemployment insurance, maternity insurance, work-related injury insurance, and housing fund plans through a PRC government-mandated benefit-contribution plan. We are required under PRC law to make contributions to employee benefit plans at specified percentages of the salaries, bonuses, and certain allowances of our employees, up to a maximum amount specified by the local government from time to time.

Our employees typically enter into standard employment contracts with us. We place a high value on recruiting, training, and retaining qualified employees. We maintain high standards on selecting and recruiting talent worldwide and provide competitive compensation packages. Remuneration packages for our employees mainly comprise base salary and performance-based bonus. To maintain and enhance the quality, knowledge and skill levels of our workforce as well as their familiarity with industry quality standards and work safety standards, we provide our employees with periodic training, including orientation programs for new employees, technical training, professional and management training and health and safety training.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE MATTERS

As an innovative biopharmaceutical company, we remain committed to a patient-centric philosophy, focusing on original innovation at its source and consistently leveraging our core strengths to pursue sustainable development. We place emphasis on and actively advance ESH management along with our business growth. We have established an ESH Committee and formulated a comprehensive policy framework encompassing environmental monitoring and risk prevention, emergency management, laboratory and biosafety, chemical management, occupational health, power outage and natural disaster response, laboratory animal management, *in vivo* experiment oversight, and quality risk management.

We are subject to various PRC laws and regulations with respect to environmental, social and governance matters. We are committed to fully complying with these PRC regulatory requirements to prevent and mitigate hazards and risks associated with our operations, while ensuring the health and safety of our employees and the surrounding communities. We have policies in place for various aspects of our operations, including R&D, sales and marketing, and manufacturing, as well as guidelines to ensure the safety of our operations and work environment. We also conduct regular checks on occupational hazards in accordance with applicable laws and regulations. In addition, we organize regular training, emergency drills, and other activities about occupational safety knowledge to enhance our employees' safety awareness and create a corporate culture that values health and safety.

During the Track Record Period and up to the Latest Practicable Date, our operations had not experienced any material incidents, and we were not aware of any claims for material personal or property damage related to health and occupational safety.

Environmental Protection

Our business is subject to national, provincial and local environmental laws, and regulations in China. The relevant laws and regulations applicable to pharmaceutical companies in China include those governing water discharge, solid waste, sewage and exhaust fumes, and hazardous substances. For more details, see "Regulatory Overview — Overview of Laws and Regulations in the PRC — Regulations in Relation to Environmental Protection and Fire Safety." We actively monitor and ensure compliance with the applicable environmental laws and regulations in China. During the Track Record Period and up to the Latest Practicable Date, we had complied with all applicable laws and regulations relating to environmental requirements in all material respects.

Our environmental protection measures mainly include:

- Promoting the efficient use of resources, minimizing waste and enhancing resource utilization throughout our office operations. During the R&D progress for our pharmaceutical products, we advocate for resource recycling, reducing the consumption of water, electricity, and gas, and regulating waste and pollutant emissions. In terms of manufacture phase of our drugs and drug candidates, we select CDMOs committed to sustainable development and require them to strictly adhere to our code of conduct, especially regarding environmental responsibility and sustainability.

- Conducting external environmental monitoring and audit to ensure our compliance with applicable environmental standards and mitigate the environmental impact of our operations;

- Developing and implementing comprehensive environmental emergency response plans designed to ensure swift and effective on-site management. These plans encompass clear protocols for immediate activation, resource mobilization, rapid assessment of potential impacts, coordinated communication with emergency responders and affected parties, and measures for containment, evacuation, and recovery. Regular testing, review, and updating of the response plans will be conducted to maintain their effectiveness and readiness for any potential environmental emergency; and

- Conducting regular and comprehensive training sessions for our employees to enhance their environmental awareness. These sessions cover key topics such as global and corporate environmental challenges, relevant laws and regulations, best practices for waste reduction and energy conservation, and the company's environmental policies and responsibilities. We also require our new employees to attend our training sessions.

As our business continues to expand, we will allocate specific environmental targets and responsibilities to each department. This approach is supported by our multi-tiered environmental management structure and the oversight of the ESH Committee, enabling continuous monitoring and effective execution of our environmental protection initiatives across the organization.

Pollutants

The main pollutants generated during our R&D process and operation activities include wastewater, waste gas and solid waste.

Wastewater

With respect to sewage discharge, we have implemented, and plan to continue implementing, various measures to comply with applicable wastewater discharge standards and reduce wastewater intensity. These measures include the adoption of advanced wastewater treatment technologies, regular monitoring and analysis of discharge quality, strict adherence to regulatory requirements, optimization of water usage processes to minimize waste. For examples, we have introduced condensate return equipment in our manufacturing facility in Wuxi for circulating water replenishment, significantly improving water reuse rates. In addition, our manufacturing facilities are equipped with steam condensate recovery systems that collect condensed steam and reuse it for preheating other equipment, further enhancing overall energy and water efficiency.

Gas

We diligently monitor the exhaust gases generated during our operations. We have installed advanced ventilation systems in our laboratory operation rooms designed to effectively capture and treat waste gases, ensuring emissions comply with regulatory standards prior to discharge. Our approach includes the implementation of separate exhaust ventilation and activated carbon adsorption technologies.

Solid waste

In solid waste disposal, we are committed to implementing responsible and sustainable waste management practices that prioritize waste reduction, segregation, recycling, and environmental compliance to minimize our ecological footprint and support long-term sustainability goals. The table below sets forth a breakdown of our solid wastes generated for the years indicated:

	Year ended December 31,		Nine months ended September 30,	
	2023	2024	2024	2025
Hazardous waste (tons)	11.1	14.3	10.6	11.5
Non-hazardous waste (tons) .	13.6	16.7	12.7	13.2

In the course of our business operations, the hazardous materials we primarily handle include chemicals and biomaterials, which may generate hazardous waste. For hazardous wastes, we have developed detailed measures to mitigate the associated safety risks:

- we have established comprehensive safety measures to mitigate associated risks, including strict segregation and clear labeling of waste types, use of secure and compatible storage containers with secondary containment, regular inspections to detect leaks or damage, and implementation of proper ventilation and temperature controls;

- we have established designated storage facilities for hazardous materials and wastes, ensuring each category is managed separately in strict accordance with standardized operational protocols;

- conducting regular training sessions on relevant laws and regulations, as well as handling and emergency response procedures in relation to hazardous materials and wastes; and

- conducting periodic emergency drills to enhance employees' response capabilities.

Greenhouse Gas Emissions

We strictly abide by applicable laws and regulations related to emissions discharges. We are committed to improving the processing efficiency of our emissions treatment facilities. The greenhouse gas emissions from our manufacturing and operations activities primarily stem from fossil fuel combustion, as well as electricity and steam consumption. The table below sets forth a breakdown of our greenhouse emissions for the years indicated:

	Year ended December 31,		For the nine months ended September 30,	
	2023	2024	2024	2025
Greenhouse gas emissions				
Scope 1 greenhouse gas (tons of CO_2 equivalent)	1,079.4	912.7	696.9	656.7
Scope 2 greenhouse gas (tons of CO_2 equivalent)	2,516.0	2,540.2	2,030.5	8,844.4
Total	**3,595.4**	**3,452,9**	**2,720.4**	**9,501.1**

To reduce carbon emissions, we are transitioning to clean energy by expanding the use of renewable resources in our operations and optimizing our energy mix to reduce carbon emissions.

Resource Consumption

We actively embrace the principle of green development by aligning closely with the national low-carbon objectives, exercising rigorous control and management across all stages from policy formulation to daily operational implementation.

In terms of energy consumption management, we have established a comprehensive policy framework encompassing environmental monitoring and risk control, emergency management, laboratory and biosafety management, chemical management, occupational health, power outage and natural disaster response, laboratory animal management, in vivo experimental management, and quality risk management. We have also implemented energy-saving measures to drive efficiency improvements, such as the installment and upgrade of energy-saving equipment.

We actively promote green office practices and environmental conservation initiatives by advocating water-saving measures in laboratory processes and daily operations, enhancing water use efficiency through equipment upgrades. In our offices, we advance digitalization and paperless operations by digitizing contracts for recruitment and procurement, as well as enabling online submission and approval of routine work requests, significantly reducing paper consumption.

Energy Saving

We are committed to expanding our business in a sustainable manner, taking into account our forecasted growth and implementation of energy-saving measures and innovations. We actively monitor our energy consumption, take proactive measures to conserve energy, and ensure thorough utilization of resources and materials.

In 2023, 2024 and nine months ended September 30, 2024 and 2025, based on our best estimates, we consumed approximately 4.5 million kWh, 4.5 million kWh, 3.6 million kWh and 10.1 million kWh of electricity and approximately 31,342 tons, 32,718 tons, 24,964 tons and 121,390 tons of water, respectively.

We make every effort to upgrade and improve energy-saving and water-saving initiatives while progressively optimizing our energy consumption structure to enhance resource and energy utilization efficiency. For example, we plan to implement, or have implemented, some photovoltaic power generation projects, aiming to increase the use of renewable energy.

Climate Change

We are committed to environmental protection, with a strong focus on reducing carbon emissions and actively addressing climate change. Through researching and promoting innovative energy-saving and emission reduction technologies, sourcing clean energy, and implementing energy-efficient measures at our offices and in the construction of future production bases, we aim to reduce greenhouse gas emissions and achieve carbon neutrality.

We recognize the profound impact climate change poses to our long-term business resilience and have integrated climate-related considerations into our governance and decision-making frameworks. We proactively identify and address climate risks, adapting our strategies to strengthen resilience. For example, we have enhanced our emergency response and contingency plans to better handle extreme weather events, mitigating potential disruptions to operations, resource availability, and safety. Moving forward, we will continue monitoring emerging climate risks, bolstering our climate management systems, expanding the use of green energy, and fostering a sustainable and responsible supply chain to improve overall climate resilience.

Social Responsibility

As a responsible corporate citizen, we are committed to consistently fulfilling our corporate social responsibilities. Guided by a people-centered philosophy, we strive to create sustainable value for all stakeholders through inclusive and responsible business practices. We place strong emphasis on employee health and well-being, recognizing them as key to long-term success. At the same time, we are committed to continuously enhancing our quality control systems to guarantee that our products consistently meet the highest standards, while rigorously adhering to ethical principles throughout our research and development processes.

Workplace Safety and Diversity

We have established and maintain a comprehensive set of rules, standard operating procedures, and measures, to ensure a healthy, safe, and inclusive environment for our employees. Our safety program emphasizes three core pillars: implementing clear guidelines for safe workplace practices, maintaining rigorous accident prevention protocols, and establishing transparent reporting procedures. We are committed to ensuring a safe and comfortable work environment with robust security and fire safety systems. Detailed emergency response plans are regularly tested through drills to proactively identify and address potential risks. In addition, we prioritize ESH management, particularly laboratory safety, with established standards for occupational disease prevention, biosafety emergency plans, safety training, and incident reporting. During the Track Record Period, we conducted 14 biosafety training sessions and four drills, and established a Biosafety Committee to oversee laboratory biosafety.

We have also adopted a board diversity policy which sets out the approach to achieve diversity of the Board. We recognize and embrace the benefits of having a diverse Board, including gender diversity, as an essential element in maintaining our competitive advantage and enhancing our ability to attract, retain and motivate employees from the widest possible pool of available talent. As of the Latest Practicable Date, around 54.3% of our total employees were female. After the [**REDACTED**], we will continue to take steps to promote gender diversity at the Board and management level. Specifically, we will actively identify female individuals suitably qualified to become our Board members. To further ensure gender diversity in a long run, our Nomination Committee will periodically review our board diversity policy and its implementation to ensure its implementation and monitor its continued effectiveness.

Supply Chain Management

Our supply chain network comprises CROs, CDMOs, and suppliers of raw materials and equipment. We strategically select partners based on five critical criteria: technical capability, cost-effectiveness, delivery performance, market reputation, and regulatory compliance. To mitigate supply chain risks — including material shortages, safety incidents, environmental violations, and integrity breaches — we maintain rigorous procurement policies. We prioritize established, large-scale suppliers who consistently demonstrate superior compliance with environmental and ethical standards. Our zero-tolerance stance against corruption and bribery is enforced through robust due diligence procedures and ongoing monitoring of all procurement activities.

Welfare and Charity Activities

We uphold the philosophy of "fostering societal enrichment and creating a shared future. "While focusing on business growth, we actively engage in various social welfare and charitable initiatives to demonstrate our corporate responsibility and promote positive social impact. During the Track Record Period, we actively participate in social welfare and charity activities.

We actively engage in community welfare through initiatives such as the "Walk for a Cause" challenge, where employees collectively contributed over 25 million steps. We also organize voluntary blood donation drives, donating 13,400 milliliters of blood during the reporting period, underscoring our commitment to saving lives. Additionally, our volunteers visit the Shanghai Children's Medical Center, providing comfort and companionship to young patients through storytelling and engaging activities, helping to ease their stress and support their recovery. We are committed to continuing to participate in charitable events to contribute to public health construction.

ESH-Related Risks Management

We place a high priority on the identification, assessment, and management of ESH-related risks. We have established a systematic risk management framework to evaluate the potential impact of ESH issues on our business operations and financial performance and to formulate corresponding mitigation measure.

We recognize that climate change poses both risks and opportunities to our business. Our operations and those of our key suppliers in the value chain could be susceptible to the following climate-related risks:

- Transition risks stem from the shift to a low-carbon economy, involving significant policy, legal, technological, and market changes. These include compliance risks from stricter environmental regulations and market risks from shifting consumer preferences towards eco-friendly products. Failure to adapt our products and operations could negatively impact our competitiveness.

- Physical risks mainly include increase costs associated with, the storage and transportation of our pharmaceutical products. Disasters created by extreme weather conditions may damage our facilities, leading to additional repair or replacement costs or resulting in temporary or long-term disclosure. They may also disrupt logistics or cause delivery delays, which, in turn, may expose us to additional costs associated with third-party liabilities.

- Opportunities: We may need to further invest in the development of green pharmaceutical products, characterized by sustainable sourcing and biodegradable packaging. We may also need to further invest in environmental and energy-saving initiatives. Any failure to address the growing market demand for eco-friendly products may affect our business, competition and damage our reputation.

We face social risks primarily related to our supply chain and workforce. Risks in our supply chain could arise from the failure of our suppliers to comply with applicable laws and our standards concerning environmental protection, labor rights, and health and safety. Our risk identification and management process involves the following key steps:

- Risk Identification. We identify and analyze potential risks from internal and external sources by taking into account our development strategy, the characteristics of the industry, and the macroeconomic environment.

- Risk Assessment. We assess the identified risks based on their nature, likelihood of occurrence, and the potential severity of their impact on our operations and strategy.

- Risk Response. Based on the assessment results, we formulate and implement targeted risk mitigation measures, which include continuously monitoring risks, updating our response plans, allocating necessary resources to ensure business continuity, and conducting relevant compliance training to enhance the risk management awareness of our employees. We have also established emergency response procedures to ensure that effective measures can be taken promptly in the event of an incident.

Governance and Oversight of ESH Matters

Our corporate governance framework is designed to facilitate sound decision-making through systems and policies aligned with our corporate values and best industry practice. We have established various specialized board committees, including strategy, audit, remuneration and evaluation, and nomination, each providing strategic guidance to our Board. In particular, we have formed a strategy and ESH committee led by operation. The committee will be responsible for (i) researching and suggesting on the company's long-term strategy, major investment decisions, and ESH-related matters; (ii) developing ESH governance vision, strategic planning, and management policies (iii) reviewing and supervising the implementation of strategic and ESH plans; (iv) ensuring the completeness and accuracy of ESH-related disclosures; and (v) other matters authorized by the Board.

Moreover, we have integrated ESH into our employee management practices to ensure that our employees contribute to our sustainability goals. For instance, to effectively manage ESH issues, mitigate risks, and achieve sustainable growth, we tie executive and managerial compensation to performance metrics related to safety, environment protection, quality, and compliance.

PROPERTIES

Owned Properties

We are headquartered in Jiangsu, China. As of the Latest Practicable Date, we owned the land use right over a parcel of land in Wuxi, Jiangsu Province, with a total site area of approximately 62,234 square meters, which is primarily used as our manufacturing facility.

Leased Properties

As of the Latest Practicable Date, we leased seven major properties in China, with an aggregate GFA of 13, 570 square meters, which are used primarily as our R&D facilities, office premises, or warehouses.

Pursuant to the applicable PRC laws and regulations, both lessors and lessees must register lease agreements with the relevant authorities and obtain property leasing filing certificates. As of the Latest Practicable Date, we had not registered six lease agreements with the relevant government authorities, while we were not subject to any penalties arising from the non-registration of lease agreements during the Track Record Period and up to the Latest Practicable Date. As advised by our PRC Legal Advisor, failure to register an executed lease agreement will not affect its validity. However, we may be subject to a fine of no less than RMB1,000 and not exceeding RMB10,000 for each unregistered lease agreement if the relevant PRC governmental authorities require us to rectify it and we fail to do so within the prescribed time period, which we do not believe would have a material adverse impact on our operation. However, we will consult with our legal advisors and aim to address the issue appropriately during the lease negotiation process in the future. As of the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of the lease agreements. For details, please see "Risk Factors — Risks Relating to Our Operations — We face certain risks relating to our leased properties, which may disrupt our operations and incur additional costs."

As of the Latest Practicable Date, no single property interest that formed part of non-property activities had a carrying amount of 15%, and no single property interest that formed part of property activities had a carrying amount of 1%, of our total assets. Therefore, according to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Cap. 32L of the Laws of Hong Kong), this Document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, which requires a valuation report with respect to our Group's interests in land or buildings.

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. Our principal insurance policies include medical insurance for our employees, clinical trial insurance, directors' and officers' liability insurance, and product liability insurance as a marketing authorization holder ("**MAH**"). See "Risk Factors — Risks Relating to our 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."

We consider that the coverage from the insurance policies maintained by us is adequate for our present operations and is in line with the industry norm. During the Track Record Period, we had not made or been the subject of any material insurance claims.

PERMITS AND LICENSES

We are subject to regular inspections, examinations and audits by local regulators and are required to maintain or renew the necessary permits, licenses and certificates for our business. As of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations and such licenses, permits and certifications all remain in full effect. For more details regarding the laws and regulations to which we are subject, see "Regulatory Overview" in this Document.

The following table sets forth the details of our material licenses, permits and approvals as of the Latest Practicable Date:

License/Permit/Approval	Issuing Authority	Holder	Grant Date	Expiration Date
Drug Manufacturing License (藥品生產許可證)	Jiangsu Provincial Drug Administration	Our Company	November 1, 2022	August 25, 2027
Drug Registration Certificate (藥品註冊證書) for golidocitinib	NMPA	Our Company	June 18, 2024	June 17, 2029
Drug Registration Certificate (藥品註冊證書) for ZEGFROVY® 150 mg	NMPA	Our Company	August 22, 2023	August 21, 2028
Drug Registration Certificate (藥品註冊證書) for ZEGFROVY® 200 mg	NMPA	Our Company	August 22, 2023	August 21, 2028

License/Permit/Approval	Issuing Authority	Holder	Grant Date	Expiration Date
Laboratory Animal Use License (實驗動物使用許可證)	Science and Technology Commission of Shanghai Municipality	Dizal Shanghai	June 8, 2023	June 7, 2028
Shanghai Filing Certificate for Pathogenic Microorganism Laboratories (BSL-2) (上海市病原微生物實驗室備案憑證(BSL-2))	Health Commission of Pudong New Area, Shanghai	Dizal Shanghai	March 2, 2018	–
Radiation Safety License (輻射安全許可證)	Shanghai Municipal Bureau of Ecology and Environment	Dizal Shanghai	June 7, 2023	June 6, 2028
U.S. FDA New Drug Application Approval	U.S. FDA	Our Company	July 2, 2025	–
Drug Manufacturing License (藥品生產許可證)	Jiangsu Provincial Drug Administration	Dizal Wuxi	December 16, 2025	December 15, 2030
Pollutant Discharge Permit (排污許可證)	Wuxi Municipal Bureau of Ecology and Environment	Dizal Wuxi	August 25, 2025	August 24, 2030

LEGAL PROCEEDINGS AND COMPLIANCE

Legal Proceedings

During the Track Record Period and up to the Latest Practicable Date, we have not been involved in any material legal or administrative proceedings that could significantly impact our operations, financial position, growth prospects, or reputation. However, similar to other companies in our industry, we may occasionally face routine claims or proceedings arising from normal business activities. For details, see "Risk Factor — Risks Relating to Our Operations — We may be involved in claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of business."

Compliance

We maintain rigorous compliance with all applicable laws and regulations governing our operations. During the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any material non-compliance incidents that led to fines, enforcement actions or other penalties that could, individually or in the aggregate, have a material adverse effect on our business, financial condition or results of operation.

RISK MANAGEMENT AND INTERNAL CONTROL

We are committed to developing and maintaining risk management and internal control systems comprised of policies and procedures tailored to our business operations. Our dedication lies in the continual enhancement of these systems to ensure their effectiveness.

Risk Management

We are exposed to various risks in our business operations, and we believe that risk management is important to our success. See "Risk Factors" for a discussion of the key risks and uncertainties we may face. We have established our risk management systems to identify, assess, monitor and mitigate the risks that may hinder our success including strategic risks, operational risks, financial risks and legal risks.

To monitor the ongoing implementation of risk management policies and corporate governance measures after the [**REDACTED**], we have adopted, or will continue to adopt, among other things, the following risk management measures.

- Our Board will continue to oversee and manage the overall risks associated with our business operations, including (i) reviewing and approving our risk management policy; (ii) reviewing and approving annual working plan and annual report of our corporate risk management; (iii) monitoring significant risks associated with our business operation; and (iv) assessing our corporate risk in the light of our corporate risk tolerance.

- Our finance, legal, human resources and other relevant departments will be responsible for implementing our risk management policy and carrying out our day-to-day risk management practice. To standardize risk management across our Group and establish a common level of transparency and performance, these departments will (i) gather information about risks related to their operations or functions; (ii) conduct risk assessments, which include identifying, prioritizing, measuring, and categorizing all key risks that could potentially impact their objectives; (iii) continuously monitor key risks related to their operations or functions; (iv) implement appropriate risk responses as needed; (v) develop and maintain mechanisms to facilitate the application of our risk management framework; and (vi) promptly report any material risks to relevant departments.

Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. We have engaged an independent internal control consultant, or the Internal Control Consultant, to perform certain agreed-upon procedures, or the Internal Control Review, in connection with the internal control of our Company and our major operating subsidiaries and to report factual findings on our Group's entity-level controls and internal controls of various processes, including financial reporting and disclosure controls, human resources and payroll management, general controls of IT system, taxation management, contract management, and other procedures of our operations. The Internal Control Consultant performed reviews on the internal control systems of our Group. As of the Latest Practicable Date, there were no material outstanding issues relating to our Group's internal control.

During the Track Record Period, we regularly reviewed and enhanced our internal control system. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement.

- We have implemented a range of measures and procedures covering various aspects of our business operations, including related party transactions, risk management, anti-bribery and anti-corruption, intellectual property protection, environmental protection, and occupational health and safety. For more information, see "— Intellectual Property" and "— Environmental, Social and Governance Matters." As part of our employee training program, we regularly provide training on these measures and procedures to our staff.

- Our Directors, who are responsible for overseeing the corporate governance of our Group, will, with assistance from our legal advisers, will periodically review our compliance status with all relevant laws and regulations following the [**REDACTED**].

- We have established an audit committee which (i) makes recommendations to our Directors on the appointment and removal of external auditors; and (ii) reviews the financial statements and renders advice in respect of financial reporting as well as oversees internal control procedures of our Group.

Anti-bribery and Anti-corruption

We maintain strict anti-bribery and anti-corruption policies for our employees and business partners, which include:

- We strictly prohibit all forms of bribery, kickbacks, excessive gifts, entertainment, or any improper payments to gain undue business advantages. This prohibition applies across all business activities involving government officials, healthcare professionals, or any third parties;

- We require distributors to uphold integrity obligations under distribution agreements;

- All sales and marketing personnel must comply with promotional requirements, including restrictions on off-label promotion. Our agreements with third-party promoters include anti-bribery clauses prohibiting any inducements to healthcare professionals or regulatory agencies; and

- We maintain accurate books and records reflecting all transactions in reasonable detail. False invoices, unusual expenses, or misleading entries are strictly prohibited and must be promptly reported.

AWARDS AND RECOGNITION

The table below sets forth a summary of the key awards and recognitions we have received.

Year	Award/Recognition	Granting Authority
2025 . . .	National "Little Giant" Enterprise Specialized in Niche Sectors (7th Batch) (第七批專精特新"小巨人"企業)	Ministry of Industry and Information Technology of the People's Republic of China (中華人民共和國工業和信息化部)
2025 . . .	First Prize of Jiangsu Provincial Science and Technology Progress Award (江蘇省科學技術進步獎一等獎)	Department of Science and Technology of Jiangsu Province (江蘇省科學技術廳)
2025 . . .	2025 Jiangsu Gazelle Enterprise (2025年江蘇瞪羚企業)	Jiangsu New-Quality Productive Forces Promotion Center (江蘇省新質生產力促進中心)
2025 . . .	Top 50 Innovative Pharmaceutical Enterprises in China (醫藥行業自主創新前五十家企業)	All-China Federation of Industry and Commerce Pharmaceutical Chamber of Commerce (全聯醫藥業商會)

Year	Award/Recognition	Granting Authority
2024 . . .	Jiangsu Provincial "Specialized, Refined, Differential and Innovative" Small and Medium-Sized Enterprise (2024年度江蘇省專精特新中小企業)	Department of Industry and Information Technology of Jiangsu Province (江蘇省工業和信息化廳)
2024 . . .	High and New Technology Enterprise Certificate (高新技術企業證書)	Department of Science and Technology of Jiangsu Province and Department of Finance of Jiangsu Province (江蘇省科學技術廳、江蘇省財政廳)