

GLOSSARY OF TECHNICAL TERMS

This glossary of technical terms contains terms used in this document in connection with us and our business. Some of these terms and their meanings may not correspond to standard industry meanings or usage of such terms.

“acute ischemic stroke” or “AIS”	a condition characterized by the sudden loss of blood circulation to an area of the brain, typically in a vascular territory, resulting in a corresponding loss of neurologic function;
“ADC”	antibody-drug conjugate, a cancer therapy combining a targeted antibody, a potent chemotherapy drug (payload), and a chemical linker, delivering chemo directly to cancer cells while sparing healthy tissue, revolutionizing targeted treatment for various cancers like breast, pancreatic, and lung cancers;
“AEs”	adverse events, any untoward medical occurrences in a patient or clinical investigation subject administered a drug or other pharmaceutical product during clinical trials and which do not necessarily have a causal relationship with the treatment;
“AIDS”	acquired immunodeficiency syndrome, defined as an HIV infection with either a CD4 ⁺ T cell count below 200 cells per μ L or the occurrence of specific diseases associated with HIV infection;
“API”	active pharmaceutical ingredient, the crucial, biologically active component in a medicine that produces the intended therapeutic effect;
“ART”	antiretroviral therapy, medications that treat HIV;
“AUC”	area under the curve;
“cART” or “combination ART”	HIV treatment regimens that involve a combination of multiple antiretroviral medications from two or more drug classes;
“CD4”	a membrane glycoprotein that is involved in the triggering of the lymphocytes by foreign antigens and also the major receptor for HIV;
“CD4 ⁺ T cells”	CD4 ⁺ T lymphocyte, a subtype (named for the presence of the CD4 protein) of T cells, which are type of white blood cell that plays key roles in coordinating the adaptive immune response by activating and directing other immune cells function;
“cell line”	a population of cells which descend from a single cell and contain the same genetic makeup, and can be propagated repeatedly;

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“Class 1 innovative drug”	a registration classification for chemical drugs implemented by the NMPA, which includes innovative drugs that have not been marketed in China or overseas and contain new compounds with clear structures, pharmacological effects and clinical values;
“C _{max} ”	maximum measured plasma concentration;
“CMO”	contract manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide drug manufacturing services;
“combination therapy” or “cocktail therapy”	treatment in which a patient is given two or more drugs (or other therapeutic agents) for a single disease;
“common COVID-19”	a clinical category of COVID-19 cases as defined under the Diagnosis and Treatment Guideline for COVID-19 (Trial Version 9) (《新型冠状病毒肺炎診療方案(試行第九版)》) published by the National Health Commission of the PRC, between the mild and severe categories;
“CRO”	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis;
“CSR”	clinical study report, standardized full report of the protocols, results, and other pertinent details of clinical studies that are typically submitted by pharmaceutical companies to regulatory authorities, as part of the drug approval process;
“CTX”	the chemotherapy drug cyclophosphamide;
“DNA”	deoxyribonucleic acid;
“DLT”	dose-limiting toxicity, which refers to adverse reactions elicited by an investigational drug that are serious enough to prevent researchers from increasing its dosage for a clinical trial, being an indicator of tolerability during dose-escalation studies;
“double-blind”	with respect to a clinical trial or study, one in which the subject(s), investigator(s), monitor and, in some cases, data analyst(s) being unaware of the treatment assignment(s);
“Dxd”	deruxtecan, a potent chemotherapy payload used in advanced ADCs;
“EGFR”	epidermal growth factor receptor;
“emergency use authorization” or “EUA”	authority granted during a public health emergency to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives;

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“first-line treatment”	the first treatment option involving medicine, prescribed by physicians after diagnosis of a disease or disorder, and in some cases, after life style management (without medicine) has failed to control or cure such disease or disorder;
“GCP”	good clinical practice;
“GFA”	gross floor area;
“GLP”	good laboratory practice;
“GMP”	good manufacturing practice;
“HIV”	human immunodeficiency virus;
“ <i>in vitro</i> ”	“in glass” in Latin, studies <i>in vitro</i> are conducted outside of a living organism in a laboratory environment using test tubes, petri dishes, etc. using components of an organism that have been isolated from their usual biological surroundings, such as microorganisms, cells or biological molecules;
“ <i>in vivo</i> ”	“within the living” in Latin, studies <i>in vivo</i> are those in which the effects of various biological entities are tested on whole, living organisms as opposed to a partial or dead organism, or those done <i>in vitro</i> ;
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China;
“INRs”	immunological non-responders, HIV-infected patients with sustained viral suppression after standard antiretroviral therapy (ART) but inadequate CD4 ⁺ T-cell immune recovery (CD4 ⁺ T-cell count persistently below 350 cells/μL)
“kinase”	a type of enzyme that catalyzes the transfer of phosphate groups from high-energy, phosphate-donating molecules to specific substrates. The protein kinases make up the majority of all kinases. Protein kinases act on proteins, phosphorylating them on their serine, threonine, tyrosine, or histidine residues. These kinases play a major role in protein and enzyme regulation as well as signalling in the cell;
“lamivudine”	a nucleoside analogue antiretroviral drug used in combination with other antiretroviral drugs to treat HIV, also known as 3TC;
“MAH”	marketing authorization holder;
“mpk”	a unit for concentration, being the amount of substance (milligram) divided by the mass of the subject (kilogram) used in the test;
“MRCT”	multi-regional clinical trial;

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“MTD”	maximum tolerated doses, each of which is the highest dose of a drug or treatment that does not cause unacceptable side effects. The MTD is determined in <i>in vivo</i> assays by testing increasing doses on different groups of animals until the highest dose with acceptable side effects is found;
“NBP”	an NMPA-approved AIS drug with the main active ingredient being a chemical constituent in celery oil with potential neuroprotective effects, also known as butylphthalide;
“NDA”	new drug application;
“NNRTIs”	non-nucleoside reverse transcriptase inhibitors, a form of ART used to treat HIV infection or AIDS;
“NRDL”	National Reimbursement Drug List of the PRC;
“NRTIs”	nucleoside reverse transcriptase inhibitors, a form of ART used to treat HIV infection or AIDS;
“NSCLC”	non-small cell lung cancer, the most common type of lung cancer making up about 85% of all cases, which may or may not be metastatic. The cells of NSCLC are larger than those of small cell lung cancer. Some types are more aggressive than others, but generally small cell lung cancer is more aggressive than NSCLC;
“nucleoside”	a compound consisting of a purine or pyrimidine base linked to a sugar, especially ribose or deoxyribose;
“PBMC”	peripheral blood mononuclear cell, any blood cell having a round nucleus, such as a lymphocyte;
“PD-1”	programmed cell death protein 1, a critical immune checkpoint receptor and a target for cancer immune checkpoint inhibitors;
“PD-L1”	programmed cell death-ligand 1, a trans-membrane protein that is considered to be a co-inhibitory factor of the immune response, it can combine with PD-1 to reduce the proliferation of PD-1 positive cells, inhibit their cytokine secretion and induce apoptosis. PD-L1 also plays an important role in various malignancies where it can attenuate the host immune response to tumor cells;
“PDC”	peptide-drug conjugate, an advanced targeted therapy that combines a tumor-targeting peptide with a potent cytotoxic drug via a linker, delivering cancer-killing agents directly to tumor cells while minimizing harm to healthy tissue, offering better tumor penetration and potentially lower toxicity than traditional chemo or even ADCs;
“per-protocol set” or “PPS”	data set generated by subjects in a clinical trial completing the study with no major protocol deviation;

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“pharmacodynamics” or “PD”	the study of how a drug affects an organism, which, together with pharmacokinetics, influences dosing, benefit and adverse effects of the drug;
“pharmacokinetics” or “PK”	the study of the bodily absorption, distribution, metabolism, and excretion of drugs, which, together with pharmacodynamics, influences dosing, benefit and adverse effects of the drug;
“Phase I”	study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness;
“Phase II”	study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage;
“Phase III”	study in which a drug is administered to an expanded patient population generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate statistically sufficient data to statistically evaluate the efficacy and safety of the product for approval and to provide adequate information for the labeling of the product;
“payload”	a highly potent, cancer-killing drug attached to a targeting antibody, designed to be released inside cancer cells to destroy them while sparing healthy tissues;
“placebo”	a substance or treatment with no active therapeutic effect, commonly used in clinical trials as the administered substance for the control group;
“PRDL”	provincial reimbursement drug list;
“preclinical studies”	preclinical studies testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether the drug is ready for clinical trials;
“receptor(s)”	a region of tissue, or a molecule in a cell membrane, which responds specifically to a particular signal, that is any of a neurotransmitter, hormone, antigen, or other substance;
“R&D”	research and development;
“RDC”	a targeted therapeutic and/or diagnostic modality that couples a targeting ligand, such as an antibody, peptide, or small molecule, to a radioactive payload via a chemical linker and chelator. Through selective delivery of radiation to diseased cells, including cancer cells, RDCs provide highly localized cytotoxic or imaging effects while limiting exposure to surrounding healthy tissues;
“RDE”	recommended dose for expansion;

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“RNA”	polymer formed from covalently linked ribonucleotide monomers;
“SAEs”	serious AEs, any untoward medical occurrence in human drug trials that at any dose: results in death; is life-threatening; requires inpatient hospitalization or causes prolongation of existing hospitalization; results in persistent or significant disability/incapacity; may have caused a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage;
“SARS”	severe acute respiratory syndrome, a viral respiratory disease caused by a SARS-associated coronavirus;
“SARS-CoV-2”	severe acute respiratory syndrome coronavirus 2, a novel coronavirus that causes COVID-19;
“SMDC”	small molecule-drug conjugates, a promising class of targeted cancer therapies. They are designed to deliver potent cytotoxic drugs directly to cancer cells while minimizing harm to normal tissues, a major limitation of traditional chemotherapy;
“T cell(s)”	a lymphocyte of a type produced or processed by the thymus gland and actively participating in the immune response, which plays a central role in cell-mediated immunity;
“TEAE”	treatment emergent adverse events, referring to an AE that occurs after administration of the study product and are therefore temporally associated with the use of the study product;
“tolerability”	the degree to which overt AEs of a drug can be tolerated by a patient. Tolerability of a particular drug can be discussed in a general sense, or it can be a quantifiable measurement as part of a clinical study;
“TRAE”	treatment-related adverse event, being an adverse event that occurs during a clinical trial and is linked to the investigational treatment;
“toxicity”	the degree to which a substance or a mixture of substances can harm humans or animals. Acute toxicity involves harmful effects in an organism through a single or short-term exposure. It is expressed generally as a dose response;
“Vif”	virion infectivity factor, a crucial HIV protein that enables the virus to replicate effectively by neutralizing the host’s antiviral defenses;
“XDC”	an acronym for conjugated drugs (or bioconjugates), a rapidly evolving and versatile class of precision cancer therapeutics. These therapies are designed to specifically target and destroy cancer cells while minimizing harm to healthy tissue, similar to “biological missiles.”