

GLOSSARY

This glossary contains explanations of certain technical terms used in this document in connection with us and our business. Such terminology and meanings may not correspond to standard industry meanings or usages of those terms.

“API”	the substance in a pharmaceutical drug that is biologically active
“ALK”	anaplastic lymphoma kinase, a type of receptor protein-tyrosine kinase
“AMD”	age-related macular degeneration, a medical condition characterized by the abnormal growth of blood vessels in the retina
“AML”	acute myeloid leukemia, a cancer of the myeloid line of blood cells
“angiogenesis”	the growth of blood vessels
“antibody-dependent cellular cytotoxicity” or “ADCC”	a mechanism of cell-mediated immune defense whereby an effector cell of the immune system actively lyses a target cell, whose membrane-surface antigens have been bound by specific antibodies
“bispecific”	antibody that combines two antigen-recognizing elements into a single construct, able to bind to two different antigens at the same time
“bioequivalence”	the relationship between two preparations of the same drug in the same dosage form that have a similar bioavailability
“biosimilar”	a follow-on version of innovator biopharmaceuticals which are separately developed after patents protecting the innovator biopharmaceuticals have expired and have similar quality, safety and efficacy as the innovator biopharmaceuticals
“BLA”	biologics license application, a request from FDA for permission to introduce, or deliver for introduction, a biologic product into interstate commerce
“CD3”	cluster of differentiation 3, a protein complex and T cell co-receptor that is involved in activating both the cytotoxic T cell and T helper cells
“CDE”	Center for Drug Evaluation, a division of the NMPA
“CDK”	cyclin dependent kinase, a conserved family of proline-directed serine/threonine kinases that perform critical roles in regulating the stepwise progression through the eukaryotic cell cycle. The major cell cycle-related CDKs include CDK1, CDK2, CDK4, and CDK6
“CDMO”	contract development and manufacturing organization
“central nervous system” or “CNS”	the brain and spinal cord
“cGMP”	current good manufacturing practice
“chemotherapy”	a category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardized regimen

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“CI”	confidence intervals
“clinical trial”	a systematic research study conducted in human subjects (patients or healthy volunteers) for validating or finding the therapeutic effects and side effects of test drugs in order to determine the therapeutic value and safety of such drugs
“CMC”	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
“c-MET”	mesenchymal-epithelial transition factor, a receptor tyrosine kinase encoded by the MET gene
“combination therapy”	treatment in which a patient is given two or more drugs (or other therapeutic agents) for a single disease
“CRO”	contract research organization
“CSCO”	Chinese Society of Clinical Oncology
“CTLA-4”	a cytotoxic T-lymphocyte-associated protein 4, which down-regulates T cell immune response to cancer cells
“EGFR”	epidermal growth factor receptor
“FDA”	U.S. Food and Drug Administration
“first-line” or “1L”	with respect to any disease, the first line therapy, which is the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment of a given type and stage of cancer. It is also called primary treatment or therapy
“FLT3”	fibromyalgia syndrome (FMS)-like tyrosine kinase 3, an important cytokine receptor involved in normal hematopoiesis
“GMP”	guidelines and regulations from time to time issued pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) as part of quality assurance
“Grade”	term used to refer to the severity of adverse events, using Grade 1, Grade 2, Grade 3, etc.
“HER2”	human epidermal growth factor receptor 2
“HIF”	hypoxia-inducible factor, transcription factors that respond to decreases in available oxygen in the cellular environment
“HR”	a statistical measure used to compare the risk of a specific event occurring between two groups, such as disease progression or death in clinical trials
“HRAS”	Harvey rat sarcoma viral oncogene homolog
“IC ₅₀ ”	half maximal inhibitory concentration, a measure of the potency of a substance in inhibiting a specific biological or biochemical function
“IDH1/2”	isocitrate dehydrogenase 1 and 2, key enzymes in cellular metabolism, epigenetic regulation, redox states, and DNA repair
“immune checkpoint inhibitors”	molecules that release the natural brakes which exist to control an immune response

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“immunogenicity”	the ability of a particular substance, such as an antigen or epitope, to provoke an immune response in the body of a human and other animal. In other words, immunogenicity is the ability to induce a humoral and/or cell-mediated immune responses
“immunotherapy”	use of the immune system to treat disease
“ <i>in vitro</i> ”	Latin for “in glass”, studies <i>in vitro</i> are conducted 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> ”	Latin for “within the living”, studies <i>in vivo</i> are those in which the effects of various biological or chemical substances 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 or clinical trial notification in Australia
“indication”	the scope or conditions for which a drug, surgical procedure, or other form of treatment is considered appropriate
“inhibitor”	a chemical or substance added or applied to another substance to slow down a reaction or to prevent an unwanted chemical change
“innovative drugs”	Category 1 chemical drugs that have not been marketed in China or overseas under the <i>Requirements for Registration Classification and Application Dossiers of Chemical Drugs</i> issued by the NMPA, representing new compounds with clear structures and pharmacological effects developed through original research and submitted for regulatory approval
“IRC”	independent review committee
“KOLs”	key opinion leaders, being physicians with influence on their peers’ medical practice, such as prescribing behavior, surgical procedures preference and residency training focus
“KRAS mutations”	subtypes of Kirsten rat sarcoma 2 viral oncogene homolog, a signal transducer protein, which plays an important role in various cellular signaling events such as in regulation of cell proliferation, differentiation and migration. Common variants include KRAS-G12C, KRAS-G12D, KRAS-G12S, KRAS-G12V, KRAS-G12R and KRAS-G13D
“lung cancer”	cancer that forms in tissues of the lung, usually in the cells lining air passages
“L858R-mutant”	a specific type of mutation in the EGFR gene, where the leucine (L) at position 858 is replaced by an arginine (R)
“MerTK”	a member of the Tyro-Axl-MerTK (TAM) family of receptor tyrosine kinases, a macrophage receptor that mediates the binding and phagocytosis of apoptotic cells, a process known as efferocytosis

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“metastatic”	in reference to any disease, including cancer, disease producing organisms or of malignant or cancerous cells transferred to other parts of the body by way of the blood or lymphatic vessels or membranous surfaces
“monoclonal antibody”	an antibody generated by identical immune cells that are all clones of the same parent cell
“monotherapy”	therapy that uses a single drug to treat a disease or condition
“NDA”	new drug application
“NMPA”	National Medical Products Administration (國家藥品監督管理局) of China, formerly known as China’s Food and Drug Administration (“CFDA”) (國家食品藥品監督管理局) or China’s Drug Administration (“CDA”) (國家藥品監督管理局); references to NMPA include CFDA and CDA
“NRAS”	neuroblastoma RAS viral oncogene homolog
“NRDL”	China’s National Reimbursement Drug List, which is also known as the <i>National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance</i> (《國家基本醫療保險、工傷保險和生育保險藥品目錄》)
“NSCLC”	non-small-cell lung cancer, any carcinoma (as an adenocarcinoma or squamous cell carcinoma) of the lungs that is not a small-cell lung carcinoma
“oncolytic virus”	a type of virus that infects and lyses (breaks down) cancer cells but not normal cells
“ORR”	overall response rate
“OS”	overall survival
“pan-RAS”	inhibitors or therapeutic agents that target all members of the RAS family of proteins, including KRAS, NRAS, and HRAS
“PD-1”	programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages
“PDGF”	platelet-derived growth factor
“PDGFR”	platelet-derived growth factor receptors
“PD-L1”	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that attaches to certain proteins on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
“PFS”	progression-free survival
“pharmacodynamics” or “PD”	the study of how a drug affects an organism, which, together with pharmacokinetic, 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

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“Phase I clinical trials”	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, excretion, and if possible, to gain an early indication of its effectiveness
“Phase II clinical trials”	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 clinical trials”	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 enough data to statistically evaluate the efficacy and safety of the product for approval, to provide adequate information for the labeling of the product
“PI”	principal investigator who leads the conduct of a clinical trial and responsible for the clinical research activities at a study site
“preclinical studies”	studies or programs 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
“PROTAC”	proteolysis targeting chimera, a molecule that can remove specific unwanted proteins. Rather than acting as a conventional enzyme inhibitor, a PROTAC works by inducing selective intracellular proteolysis
“pmCNV”	pathologic myopic choroidal neovascularization
“RCC”	renal cell carcinoma
“refractory”	when used in reference to any type of cancer, cancer that does not respond to treatment or it may become resistant during treatment
“registrational trial”	the final controlled trial or study to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval
“relapsed”	when used in reference to any disease, including cancer, the return of a disease or the signs and symptoms of a disease after a period of improvement
“RVO”	retinal vein occlusion, a common vascular disorder of the retina
“SD”	stable disease. In oncology, it refers to cancer that is neither decreasing nor increasing in extent or severity
“second-line” or “2L”	with respect to any disease, the therapy or therapies that are tried when the first-line treatments do not work adequately
“solid tumor”	an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors may be benign (not cancer), or malignant (cancer). Different types of solid tumors are named for the type of cells that form them. Examples of solid tumors are sarcomas, carcinomas, and lymphomas

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“standard of care”	treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals
“TEAD”	TEA domain family of transcription factors
“toxicity”	the degree to which a substance or a mixture of substances can harm humans or animals
“tumors”	an abnormal growth of tissue resulting from uncontrolled, progressive multiplication of cells
“tyrosine kinase inhibitor” or “TKI”	a pharmaceutical drug that inhibits tyrosine kinases
“VEGF” or “VEGFR”	vascular endothelial growth factor, a gene critical for the growth and development of cancer cells. Vascular endothelial growth factor receptor (VEGFR) refers to a family of receptor tyrosine kinases that mediate the biological effects of VEGF
“VHL”	von Hippel-Lindau
“wAMD”	one of two types of age-related macular degeneration, which can lead to sudden and severe vision loss and is the most advanced form of AMD