

GLOSSARY OF TECHNICAL TERMS

This glossary contains definition of certain terms used in this Document in connection with us and our business. Some of these may not correspond to standard industry definitions.

“AE” or “adverse event”	any untoward medical occurrences in a patient or clinical investigation subject who has been administered with a drug or other pharmaceutical product during clinical trials and which do not necessarily have a causal relationship with the treatment
“Allogeneic CAR-T Cell Therapy”	a type of CAR-T therapy where the T cells are derived from a healthy donor (rather than the patient), modified <i>ex vivo</i> , and then administered to the patient.
“Autologous CAR-T Cell Therapy”	a type of CAR-T therapy where the patient’s own T cells are collected, genetically modified <i>ex vivo</i> to express a CAR, expanded, and then reinfused into the same patient.
“antigen”	the substance that is capable of stimulating an immune response, specifically activating lymphocytes, which are the body’s infection-fighting white blood cells
“ASGCT”	American Society of Gene & Cell Therapy
“ASH”	American Society of Hematology
“autoimmune disease”	a condition that results from an anomalous response of the adaptive immune system
“B-cell” or “B cell”	a type of white blood cell that differs from other types of lymphocytes by expressing B cell receptors on its surface, and responsible for producing antibodies
“BCMA”	B cell maturation antigen, a protein that is highly expressed in a number of hematologic malignancies
“BLA”	biologics license application
“BIC” or “Best-in-Class”	it describes a drug candidate that, based on available data, appears to have superior efficacy, safety, or other key attributes compared to other therapies in the same class or for the same indication.
“CAR(s)”	chimeric antigen receptor(s)
“CAR-T” or “CAR T”	chimeric antigen receptor T cell
“CD19”	a cell surface protein expressed on the surface of almost all B cell leukemia and lymphoma
“CDE”	Center for Drug Evaluation, an institution under the NMPA

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“CDMO(s)”	contract development manufacturing organization(s), a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing
“(c)GMP”	(current) good manufacturing practices
“chemotherapy”	a category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardized regimen
“CLDN18.2”	Claudin 18.2, an attractive target in the treatment of certain solid tumors such as gastric cancer, esophageal cancer and pancreatic cancer
“CMC”	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
“cohort”	a group of patients as part of a clinical study who share a common characteristic or experience within a defined period and who are monitored over time
“CR”	complete response, the disappearance of all signs of cancer in response to treatment
“CRO(s)”	contract research organization(s), a company provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research and development services outsourced on a contract basis
“CRS”	cytokine release syndrome, a form of systemic inflammatory response syndrome that arises as a complication of some diseases or infections, and is also an adverse effect of some monoclonal antibody drugs, as well as adoptive T cell therapies
“CSCO”	Chinese Society of Clinical Oncology
“CSO(s)”	contract sales organization(s), a company that provides various services and solutions related to pharmaceutical marketing and commercial activities under contracts with pharmaceutical or biotech companies
“CTC(s)” or “Circulating Tumor Cell”	a cell that has shed into the vasculature from a primary tumor and is carried in the bloodstream, potentially leading to metastasis
“cytokine”	a broad and loose category of small proteins that are important in cell signaling. Their release has an effect on the behavior of cells around them
“cytotoxic”	toxic to living cells

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“DC”	a dendritic cell is an antigen-presenting cell which is also known as an accessory cell of the mammalian immune system.
“DCR”	disease control rate
“DLBCL”	Diffuse large B-cell lymphoma, a common type of non-Hodgkin’s lymphoma that starts in lymphocytes
“DLT”	dose-limiting toxicity
“DOR”	duration of response
“ECOG”	Eastern Cooperative Oncology Group, one of the first publicly funded cooperative groups to perform multicenter clinical trials for cancer research
“EOP1”	a formal, Type B (FDA) or Type II (NMPA) meeting conducted after Phase I trials. It facilitates crucial discussions on Phase II or registrational study design, CMC and, for specific serious diseases, accelerates development, aiming for alignment on study goals.
“EpCAM”	epithelial cell adhesion molecule, which is a protein on epithelial cell surfaces that helps with cell-to-cell binding, but also has complex roles in cell growth, signaling, and migration, acting as a marker for many cancers because it’s overexpressed in tumors, making it useful for diagnosis and potential therapy.
“ <i>ex vivo</i> ”	outside of the living body
“FOCO-CAR”	Immunofoco’s proprietary FOCO-CAR platform, a technology for producing CAR-T cell therapies
“FOLFIRINOX”	a chemotherapy combination used mainly for advanced pancreatic cancer, named from the initials of its four drugs: leucovorin calcium, fluorouracil (5-FU), irinotecan, and oxaliplatin, which work together to destroy rapidly dividing cancer cells
“GC”	gastric cancer
“GCP”	good clinical practice
“GEJ”	gastroesophageal junction
“GI”	gastrointestinal
“hematological malignancies”	cancers affecting blood-forming tissues like bone marrow or immune system cells, primarily categorized as leukemia, lymphoma, and multiple myeloma

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“HER2”	human epidermal growth factor receptor 2, a protein involved in normal cell growth; HER2 may be made in larger than normal amounts by some types of cancer cells, including breast, ovarian, bladder, pancreatic, stomach, and esophageal cancers
“IIT” or “investigator-initiated trial”	clinical trial sponsored and conducted by independent investigators
“immunotherapy”	use of the immune system to treat disease
“ <i>in vitro</i> ”	studies are performed with microorganisms, cells, or biological molecules outside their normal biological context
“ <i>in vivo</i> ”	those in which the effects of various biological entities are tested on whole, living organisms or cells, usually animals, including humans, and plants, as opposed to a tissue extract or dead organism
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China
“KOL(s)” or “key opinion leader(s)”	a trusted, well-respected influencer with proven experience and expertise in a particular field; in healthcare, these thought leaders could be physicians, hospital executives, health system directors, researchers, patient advocacy group members, and more
“lentivirus”	a genus of retroviruses. Due to their rather flexible genome and a potential of transducing many forms of cells, lentiviruses have become one of the most widely used vectors for gene transfer
“LNP” or “lipid nano-particle”	a tiny, spherical delivery system made of fats that carries drugs or genetic material (like mRNA or siRNA) into cells
“LVV”	lentiviral vector
“lymphocytes”	a sub-type of white blood cells, such as T cells, B cells and NK cells
“mAb” or “monoclonal antibody”	antibodies that are made by identical immune cells which are all clones belonging to a unique parent cell
“metastatic”	in reference to any disease, including cancer, disease producing organisms or of malignant or cancerous cell transferred to other parts of the body by way of the blood or lymphatic vessels or membranous surfaces
“monotherapy”	therapy that uses a single drug to treat a disease or condition

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“mOS”	median overall survival, the length of time from either the date of diagnosis or the start of treatment for a disease that half of the patients in a group of patients diagnosed with the disease are still alive
“mPFS”	median progression-free survival; the time at which 50% of patients in a study group have experienced disease progression or death
“MxV-G” or “MxV glycoprotein”	The MxV glycoprotein is a fusogenic protein that mediates membrane fusion between the virus and the target cell. MxV belongs to the vesiculovirus genus of the Rhabdoviridae family and is genetically distinct from, yet shares partial homology with, the prototypical vesicular stomatitis virus (VSV)
“NC”	non-clinical
“NDA”	new drug application
“NHL”	non-Hodgkin’s lymphoma
“NK”	natural killer cell, the human body’s first line of defense due to their innate ability to rapidly seek and destroy abnormal cells
“NKG2D”	a crucial activating immune receptor on Natural Killer (NK) cells and certain T cells
“NRDL”	National Reimbursement Drug List
“neurotoxicity”	possible adverse side effect of a therapy that leads to a state of confusion, aphasia, encephalopathy, tremor, muscular weakness, and somnolence
“oncology”	a branch of medicine that deals with tumors, including study of their development, diagnosis, treatment and prevention
“On-target off-tumor Toxicity”	toxicity caused to non-cancerous cells that express the same antigen by an antigen-directed therapy when the relevant antigen is expressed to some extent on normal tissues in addition to tumor cells
“Orphan Drug Designation”	a designation by the FDA for drugs, biologics, or medical devices intended to prevent, diagnose, or treat rare conditions
“ORR”	overall response rate, the proportion of patients who have a partial or complete response to therapy
“OS”	overall survival, the length of time from diagnosis or treatment start that patients with a disease, typically cancer, remain alive, regardless of cause of death or disease progression

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“PC”	pancreatic cancer
“PCT”	Patent Cooperation Treaty
“PD” or “pharmacodynamics”	pharmacodynamics, the study of how a drug affects an organism, which, together with pharmacokinetics, influences dosing, benefit, and adverse effects of the drug
“PD-1”	programmed cell death protein 1 or programmed death receptor 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages.
“PD-L1”	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that attaches to PD-1 on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
“Phase I clinical trial”	a 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 Ib clinical trial”	an expansion part of the Phase 1 clinical trial conducted at the selected dose level(s) or selected indication(s) to further evaluate safety, tolerability, PK/PD, and preliminary efficacy in specific patient populations, and to further evaluate the proposed recommended Phase 2 dose (RP2D)
“Phase IIa clinical trial”	an early Phase II clinical trial that focuses on a proof-of-concept assessment of efficacy and safety in a small number of patients
“Phase II clinical trial”	a 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 drug for a specific targeted disease, and to determine dosage tolerance and optimal dosage
“Phase III clinical trial”	a large-scale study (hundreds to thousands of people) that confirms a new treatment’s effectiveness, monitors side effects, compares it to current standard treatments (or placebo), and gathers data for regulatory approval, determining the drug’s overall risks and benefits before it can be marketed
“PI(s)” or “principal investigator(s)”	the individual responsible for the conduct of a clinical study at a site
“PK” or “pharmacokinetics”	pharmacokinetics, 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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“pre-clinical studies”	pre-clinical studies testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetics and safety information and to decide whether the drug is ready for clinical trials
“RECIST 1.1”	the standard guideline used in oncology clinical trials to objectively measure how solid tumors respond to treatment, classifying outcomes as Complete Response (CR), Partial Response (PR), Stable Disease (SD), or Progressive Disease (PD) by tracking changes in the size (longest diameter) of target lesions
“refractory”	disease that is resistant at the beginning of treatment or becomes resistant during treatment
“Regenerative Medicine Advanced Therapy” or “RMAT”	a special status granted by the FDA to regenerative medicine therapies, including cell therapies, intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition
“registrational trial”	the final controlled trial or study to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval
“relapsed”	the return of a disease or the signs and symptoms of a disease after a period of improvement
“RP2D”	recommended Phase II dose
“scFv” or “Single-chain Variable Fragment”	a small, engineered protein that combines the antigen-binding parts (variable regions) of an antibody’s heavy (VH) and light (VL) chains, connected by a flexible peptide linker, maintaining specificity but offering smaller size
“second-line” or “2L”	with respect to any disease, the therapy or therapies that are tried when the first-line (initial) treatments do not show adequate efficacy
“SLE”	systemic lupus erythematosus
“SNR(s)”	synthetic NKG2D receptor
“solid tumors”	an abnormal mass of tissue that usually does not contain cysts or liquid areas
“standard of care” or “SOC”	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

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“TAA”	a Tumor-Associated Antigen (TAA), which is a molecule found on cancer cells that triggers an immune response, either overexpressed or abnormally expressed compared to normal cells, serving as potential targets for cancer diagnosis and immunotherapy like vaccines or antibody therapies
“T-cell” or “T cell”	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. T cells can be distinguished from other lymphocytes, such as B cells and NK cells, by the presence of a T cell receptor on the cell surface
“third-line” or “3L”	with respect to any disease, the therapy or therapies that are tried when the second-line treatments do not show adequate efficacy
“3+3 design” or “3+3 dose escalation design”	a standard rule-based dose escalation study design used in clinical trials to determine the maximum tolerated dose (MTD). Under this design, patients are initially enrolled in cohorts of three. If no DLT is observed among the initial three patients, the trial proceeds to enroll patients at the next higher dose cohort. If one out of the three patients experiences a DLT, three additional patients are enrolled at that same dose level. If two or more patients out of a maximum of six experience a DLT at a specific dose level, the MTD is deemed to have been exceeded, and further dose escalation ceases. The MTD is therefore defined as the highest dose level at which no more than one out of six patients experiences a DLT
“TNBC”	triple-negative breast cancer
“toxicity”	the degree to which a substance or a mixture of substances can harm humans or animals
“treatment-related adverse event” or “TRAЕ”	undesirable events not present prior to medical treatment or an already present event that worsens in intensity or frequency following the treatment
“VHH”	Variable heavy chain of heavy domain, a small antigen-binding fragment derived from unique heavy-chain-only antibodies, which consist of a single monomeric variable domain, making them highly stable, soluble and effective for reaching hidden epitopes
“xenografts”	a transplant of tissue, organs, or cells from one species to another, primarily used in medical research, especially oncology, and temporary wound treatment, serving as models for disease and drug testing