GLOSSARY OF TECHNICAL TERMS

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

"adverse event" or "AE"	any untoward medical occurrence in a participant administered a pharmaceutical product, which does not necessarily have a causal relationship with the trial intervention
"advanced cancer"	a stage of cancer in which the disease is unlikely to be cured with current standard treatments, often including metastatic or locally advanced tumors
"antibody drug conjugates" or "ADCs"	therapeutics composed of a monoclonal antibody linked to a biologically active cytotoxic drug, designed to selectively target and kill cancer cells
"antigen"	a molecule or molecular structure, often on the surface of a cell or pathogen, that can be recognized by the immune system, particularly by antibodies or T cells
"biomarker"	a measurable indicator of a biological state or condition, often used to assess disease progression or response to treatment
"bispecific antibody"	an engineered antibody capable of simultaneously binding to two different antigens or epitopes
"BLA"	a biologics license application submitted to regulatory authorities to request approval for marketing a biological product
"CAGR"	compound annual growth rate
"CAR-T"	chimeric antigen receptor T-cell therapy, a type of immunotherapy in which a patient's T cells are genetically modified to recognize and kill cancer cells
"CDE"	Centre for Drug Evaluation of the NMPA, responsible for reviewing and approving clinical trial applications and new drug registrations in China
"CDMO"	contract development and manufacturing organization, a company that provides drug development and manufacturing services on a contract basis
"CMC"	activities related to chemistry, manufacturing, and quality control of drug development

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"cohort"	a group of patients as part of a clinical trial who share a common characteristic or experience within a defined period and who are monitored over time
"cold (tumor)"	a tumor with low levels of immune cell infiltration and low immunogenicity, often less responsive to immunotherapies
"combination (therapy)"	the use of two or more drugs or treatment modalities simultaneously to manage or treat a disease, often to enhance efficacy, reduce resistance, or minimize side effects
"contract research organization" or "CRO"	a company that provides outsourced research services to pharmaceutical, biotechnology, and medical device companies, including preclinical research, clinical trial management, and regulatory support
"chemotherapy"	a type of cancer treatment using chemical agents to kill or inhibit the growth of rapidly dividing cells
"complete response" or "CR"	the disappearance of all signs of cancer in response to treatment, with any pathological lymph nodes (whether target or non-target) reduced in short axis to <10 mm, according to RECIST 1.1 criteria
"complete response rate" or "CRR"	the proportion of patients in a clinical trial who achieve a complete response (CR) to treatment
"cytokine"	small proteins secreted by cells, especially immune cells, that mediate and regulate immunity, inflammation, and hematopoiesis
"cytotoxic" or "cytotoxicity"	the quality of being toxic to cells, often causing cell damage or cell death
"disease control rate" or "DCR"	the proportion of patients who achieve complete response, partial response, or stable disease after treatment
"dose-limiting toxicity" or "DLT"	a side effect of a drug or treatment that prevents an increase in dose
"duration of response" or "DOR"	the period of time during which a tumor continues to respond to treatment without progression
"early-line"	a treatment administered at the early stages of disease management, typically before late-line therapies
"ECOG PS 1–3"	Eastern Cooperative Oncology Group performance status 1-3, a scale to assess a patient's daily living abilities, with higher numbers indicating greater disability
"EDC system"	electronic data capture system, software used to collect, manage, and store clinical trial data electronically

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"ELISA"	enzyme-linked immunosorbent assay, a laboratory technique used to detect and quantify proteins, antibodies, or antigens in a sample
"ERP"	enterprise resource planning, a type of software used by organizations to manage business processes
"EOP1"	end of Phase I meeting with regulatory authorities to discuss Phase I trial results and Phase II plans
"*ex vivo*"	outside a living organism, in a controlled environment, typically referring to experiments on tissues or cells removed from the organism
"FDA"	the U.S. Food and Drug Administration, responsible for ensuring the safety, efficacy, and quality of drugs, biologics, and medical devices
"first-line"	the initial or primary treatment given for a disease, typically the standard of care
"freedom-to-operate analysis" or "FTO Analysis"	a legal assessment to determine whether a product or process can be commercialized without infringing third-party intellectual property rights
"good clinical practice" or "GCP"	a set of international ethical and scientific quality standards for designing, conducting, and reporting clinical trials to protect participants and ensure data integrity
"good laboratory practice" or "GLP"	a set of principles intended to assure the quality and integrity of non-clinical laboratory studies
"good manufacturing practice" or "GMP"	a system of regulations and guidelines that ensures pharmaceutical and biotech products are consistently produced and controlled to meet quality, safety, and efficacy standards
"Grade"	a classification of the severity of adverse events, typically following standardized criteria such as CTCAE
"head and neck squamous cell carcinoma" or "HNSCC"	cancer arising from the squamous cells lining the mucosal surfaces of the head and neck region
"hot (tumor)"	a tumor with high levels of immune cell infiltration and immunogenicity, often more responsive to immunotherapies
"human leukocyte antigen" or "HLA"	a set of cell-surface proteins that regulate immune responses by presenting antigens to T cells
"IFN-γ"	interferon-gamma, a cytokine important for innate and adaptive immunity against infections and cancer

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"IL-2"	interleukin-2, a cytokine that promotes the growth, differentiation, and survival of T cells
"indications"	specific diseases or conditions for which a drug or therapy is approved or intended to be used
"immune checkpoint inhibitor" or "ICI"	a type of immunotherapy that blocks proteins used by cancer cells to suppress immune responses
"immunogenic cell death" or "ICD"	a form of cell death that elicits an immune response, often triggered by certain cancer treatments, and contributes to tumor cell killing and immune system activation
"immunotherapy"	treatment that leverages or modulates the immune system to fight disease, particularly cancer
"immune cell"	a cell involved in the body's immune response, such as T cells, B cells, NK cells, or macrophages
"IND"	a request for authorization to administer an investigational drug or biological product to humans
"inhibitor"	a substance that blocks or reduces the activity of a specific enzyme, receptor, or cellular pathway
"*in vitro*"	Latin for "within the glass", referring to studies that are performed with microorganisms, cells, or biological molecules outside their normal biological context
"*in vivo*"	Latin for "within the living", referring to studies 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
"immune-related adverse event" or "irAE"	an adverse event caused by overactivation of the immune system during immunotherapy
"independent radiology review committee" or "IRC"	a panel of radiologists who independently assess imaging data in clinical trials to ensure unbiased evaluation of tumor response
"investigator-initiated trial" or "IIT"	a clinical trial designed and conducted by a physician or investigator rather than a sponsor company
"IL-2 supplementation"	the administration of interleukin-2 to enhance immune cell proliferation or function, often in immunotherapy
"melanoma"	a type of skin cancer that develops from melanocytes, cells that produce pigment

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"metastatic"	describing cancer that has spread from its primary site to other parts of the body
"microsatellite instability-high" or "MSI-H"	a biomarker indicating defects in DNA mismatch repair and potential sensitivity to certain immunotherapies
"monotherapy"	a treatment regimen involving only one therapy, without combination with other drugs
"MTD"	maximum tolerated dose, the highest dose of a drug that does not cause unacceptable side effects
"MHC"	major histocompatibility complex, a set of cell surface proteins essential for antigen presentation and immune recognition
"NDA"	new drug application, a request submitted to regulatory authorities for approval to market a new drug
"NK cell"	natural killer cell, a type of lymphocyte that can recognize and kill virus-infected or tumor cells without prior sensitization
"NMPA"	National Medical Products Administration, the regulatory authority in China responsible for drug, device, and biologics approval
"NSCLC"	non-small cell lung cancer, the most common type of lung cancer, encompassing several histological subtypes such as adenocarcinoma, squamous cell carcinoma, and large cell carcinoma
"objective response rate" or "ORR"	the proportion of patients with a partial or complete response to treatment
"oncology"	the branch of medicine that focuses on the study, diagnosis, and treatment of cancer
"partial response" or "PR"	at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters, according to RECIST 1.1 criteria
"PD-1"	programmed cell death protein 1, an immune checkpoint receptor on T cells that downregulates immune responses
"PD-(L)1"	programmed cell death protein 1 or its ligand PD-L1, molecules targeted by immune checkpoint inhibitors
"pharmacodynamics" or "PD"	the study of how a drug affects the body, including its mechanism of action, therapeutic effects, and potential side effects

"pharmacokinetics" or "PK"	the study of how a drug is absorbed, distributed, metabolized, and eliminated by the body, providing crucial information on the drug's behavior and dosing regimen
"Phase I clinical trial"	an early-stage clinical trial assessing safety, tolerability, pharmacokinetics, and optimal dosing of a new drug in a small group of participants
"Phase II clinical trial"	a clinical trial assessing preliminary efficacy, dosing, and safety in a larger group of participants
"Phase III clinical trial"	a late-stage clinical trial comparing a new treatment to standard treatment or placebo in a large population to confirm efficacy and safety
"postoperative adjuvant therapy"	an additional cancer treatment given after the primary surgical removal of a tumor for relapse prevention
"primary endpoint"	the main outcome measure used in a clinical trial to determine the effect of a treatment, reflecting the primary objective of the study, such as overall survival or disease progression
"progression-free survival" or "PFS"	the length of time during and after treatment that a patient lives without disease progression
"rapid expansion protocol" or "REP"	a procedure to expand T cells, such as TILs, to clinically relevant numbers for adoptive cell therapy, typically using cytokine stimulation and feeder cells while maintaining cell functionality and viability
"RECIST 1.1"	Response Evaluation Criteria in Solid Tumors, version 1.1, a standardized set of guidelines for assessing tumor response to treatment in clinical trials
"refractory"	cancer or disease that does not respond to standard treatments
"registrational trial"	a clinical trial intended to provide definitive evidence of efficacy and safety to support regulatory approval
"RP2D"	recommended Phase II dose, the dose identified in Phase I trials for use in subsequent studies based on safety and efficacy
"serious adverse event" or "SAE"	an adverse event that results in death, hospitalization, disability, or other significant medical consequences
"site management organization" or "SMO"	a company that supports clinical trial sites in patient recruitment and trial management

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"solid tumor"	cancer that form a mass or lump, as opposed to hematological malignancies
"stable disease"	a state in which cancer neither decreases nor increases significantly in extent or severity
"System Organ Classes" or "SOCs"	a classification of adverse events in clinical trials according to the organ system affected
"T cell"	a type of lymphocyte that plays a central role in cell-mediated immunity
"T-cell receptor" or "TCRs"	a complex of proteins on the surface of T cells that recognizes specific antigens presented by MHC molecules
"TCR-T therapy"	a form of adoptive cell therapy in which T cells are engineered to express specific T-cell receptors targeting tumor antigens
"TGF-β"	transforming growth factor beta, a cytokine involved in regulation of cell growth, differentiation, and immune responses
"toxicity"	the degree to which a substance can cause harmful effects to an organism or its cells
"treatment-emergent adverse events" or "TEAEs"	adverse events that occur during treatment, regardless of whether they are drug-related or the severity
"tumor-infiltrating lymphocyte" or "TIL"	an immune cell found within tumors that can recognize and attack cancer cells