

GLOSSARY OF TECHNICAL TERMS

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

“3+3 design”	a dosing method where three patients are initially enrolled into a given dose cohort. If there is no dose-limiting toxicity (“DLT”) seen in any of these participants, the trial proceeds to enroll additional participants into the next higher dose cohort. If one patient manifests a DLT at a specific dose, an additional three individuals are accrued into that same dose cohort. Development of DLTs in two or more out of six patients at a specific dose level indicates that the maximum tolerated dose (“MTD”) has been exceeded; further dose escalation is not pursued, and the prior dose level is expanded to six patients; if there is no more than one patient who experiences a DLT among those six patients, that dose level is considered the MTD
“ADA”	anti-drug antibodies
“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
“AESI”	adverse event of special interest, AE of scientific and medical concern specific to the sponsor’s product
“antibody”	also known as an immunoglobulin, a protein used by the immune system to recognize and bind an antigen
“AFP”	alpha-fetoprotein, liver tumor biomarker
“BLA”	Biologics License Application, the submission to the U.S. FDA seeking approval to market a biologic product in the United States
“CAGR”	compound annual growth rate
“CD3”	Cluster of differentiation 3
“CDMO”	contract development and manufacturing organization, a pharmaceutical company that develops and manufactures drugs for other pharmaceutical companies on a contractual basis
“CAR-T”	chimeric antigen receptor T-cell

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“chemotherapy”	a category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardized regimen
“clinical trial”	a research study carried out in human 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
“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
“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, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“CRS”	cytokine release syndrome, an acute systemic inflammatory response characterized by the excessive and uncontrolled release of proinflammatory cytokines following immune activation
“dAb”	domain antibody, an antibody fragment consisting of a single monomeric variable antibody domain
“DCR”	disease control rate, the proportion of patients who have achieved either a complete response, partial response, or stable disease after treatment
“DLT”	dose-limiting toxicity, side effects of a drug that are serious enough to prevent an increase in dose
“DoR”	duration of response, the length of time that a tumor continues to respond to treatment without the cancer growing or spreading
“ECOG score”	Eastern Cooperative Oncology Group score, a scale from 0 to 4 (sometimes 5) used to measure a patient’s physical functioning and ability to perform daily activities, with lower scores indicating a higher level of function
“EGFR”	epidermal growth factor receptor, a cell surface protein that plays a key role in cellular signaling and growth

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“Fc”	Fragment crystallizable, the tail portion of an antibody that interacts with immune cells and complement system proteins to trigger immune responses
“FGL-1”	fibrinogen-like protein 1, an immune suppressive molecule that inhibits antigen-specific T-cell activation by acting as a major ligand of LAG-3
“FTO Analysis”	the freedom-to-operate searches and analyses
“FOLR1”	folate receptor alpha, also known as FR α , is a glycosylphosphatidylinositol (GPI)-anchored membrane glycoprotein that mediates the high-affinity binding and cellular uptake of folate and reduced folate derivatives through receptor-mediated endocytosis
“GCP”	good clinical practice, an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans
“GLP”	good laboratory practice, a quality system of management controls for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical (including pharmaceuticals) non-clinical studies
“GMP”	good manufacturing practice, the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of products
“Grade,” which is in relation to AE	term used to refer to the severity of adverse events according to Common Terminology Criteria for Adverse Events (CTCAE), using Grade 1, Grade 2, Grade 3, etc
“HCC”	hepatocellular carcinoma
“HNSTD”	highest non-severely toxic dose, the highest dose level that does not produce lethal, life-threatening, or irreversible toxicities
“ICI”	immune checkpoint inhibitor, a type of immunotherapy that block immune checkpoint proteins from binding with partner proteins
“IFN- γ ”	interferon-gamma
“IIT”	investigator-initiated trial
“immunotherapy”	use of the immune system to treat disease

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“indication”	a specific condition, disease, or medical purpose for which a drug, treatment, or medical device is intended or approved for use
“LAG-3”	lymphocyte activation gene 3
“mechanism of action”	the specific biochemical interaction through which a drug substance produces its pharmacological effect
“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
“monotherapy”	therapy that uses a single drug to treat a disease or condition
“msAb”	multispecific antibody, an antibody that is able to recognize two or more epitopes located on the same or distinct targets
“MTD”	maximum tolerated dose, the highest dose of a drug or treatment that does not cause unacceptable side effects
“MMPs”	matrix metalloproteinases
“NAb”	neutralizing antibody
“NCCN”	National Comprehensive Cancer Network
“NCI”	National Cancer Institute
“NDA”	new drug application, a process required by a regulatory authority to approve a new drug for sale and marketing
“NIH”	National Institutes of Health
“NSCLC”	non-small-cell lung carcinoma, any carcinoma (as an adenocarcinoma or squamous cell carcinoma) of the lungs that is not a small-cell lung carcinoma
“OBD”	optimal biological dose, the lowest dose with the highest rate of efficacy while safe
“ORR”	overall response rate, the proportion of patients who have a partial or complete response to therapy
“OS”	overall survival, a length of time that a patient with a specific disease is still alive, used as a measurement of a drug’s effectiveness
“PD”	pharmacodynamics, the study of the effects of the drug on the human body

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“PD-1”	programmed death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages, acting to turn off the T cell mediated immune response as part of the process that stops a healthy immune system from attacking other pathogenic cells in the body
“PD-L1”	programmed death-ligand 1, 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
“PFS”	progression-free survival, the length of time during and after the treatment of a disease, such as cancer, that a patient lives without the disease getting worse. In a clinical trial, measuring the progression-free survival is one way to see how well a new treatment works
“Phase I clinical trial(s)”	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 I clinical trials can be divided into Phase Ia and Phase Ib clinical trials. Phase Ia typically involves dose-escalation studies, while Phase Ib generally focuses on combination therapy or dose-expansion studies
“Phase II clinical trial(s)”	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 trial(s)”	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
“PK”	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
“PIs”	principal investigators, the key individual responsible for the overall design, conduct, and management of clinical trials
“preclinical studies”	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

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“primary endpoint”	the main or most important outcome at the end of a study to assess the effect of the drug being investigated
“R&D”	research and development
“RAS”	rat sarcoma, a family of proteins that are critical regulators of cellular signaling pathways; it primarily includes HRAS, KRAS, and NRAS
“RP2D”	recommended Phase II dose, the dosage of a drug that is suggested for use in Phase II clinical trials
“SAE”	serious adverse events
“secondary endpoint”	additional events of interests which the study is not specifically powered to assess
“SD”	stable disease, a situation where a patient’s cancer does not significantly worsen or improve after treatment
“SMC”	the safety monitoring committee
“TAAs”	tumor associated antigens
“TCE”	T-cell engager
“TCM”	T-cell modulator, an agent that modulates the activity of T cells to treat diseases
“TCR”	T-cell receptor
“TEAE”	treatment emergent adverse event, adverse events not present prior to medical treatment, or an already present event that worsens either in intensity or frequency following the treatment
“TKI”	tyrosine kinase inhibitor, a type of EGFR-targeted therapy
“TME”	tumor microenvironment, the highly dynamic and heterogeneous milieu surrounding tumor cells, composed of both cellular and non-cellular components that interact to influence tumor initiation, progression, and therapeutic response
“TNBC”	triple-negative breast cancer
“toripalimab”	an anti-PD-1 antibody for the treatment of indications including multiple solid tumors, developed by Junshi

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“TRAE”	treatment-related adverse event, undesirable events not present prior to medical treatment or an already present event that worsens in intensity or frequency as a result of the treatment
“uPA”	urokinase-type plasminogen activator, a protease commonly overexpressed in many type of cancers and measurable in patients, providing a practical biomarker for patient identification and monitoring treatment response
“SCLC”	small cell lung cancer
“zero-order immune cytotoxicity”	the capability of the activated T cells to kill tumor cells at a steady rate, regardless of the amount of tumor cells or tumor antigens engaged by the TCEs