

GLOSSARY OF TECHNICAL TERMS

This glossary of technical terms contains explanations of certain technical terms used in this document in connection with our Group and our business. These terms and their meanings may not correspond to standard industry meanings or usage of these terms.

“Active TED”	active thyroid eye disease, marked by active inflammation and rapid symptom progression including pain, swelling, and visual disturbances
“AD”	atopic dermatitis, a chronic, relapsing inflammatory skin disease, which is the most common form of eczema
“ADA”	anti-drug antibody, an antibody produced by the immune system against a biologic. ADAs may adversely affect the efficacy and safety of the biologic
“ADC”	antibody-drug conjugate, a class of biopharmaceutical drugs that comprise an antibody conjugated to a payload molecule, typically a cytotoxic agent, via a chemical linker
“ADCC”	antibody dependent cell-mediated cytotoxicity or antibody-dependent cellular cytotoxicity, 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
“AE”	adverse event, which may be mild, moderate, or severe, any untoward medical occurrence in a patient or subject receiving a drug or other pharmaceutical product in a clinical trial and which does not necessarily have a causal relationship with the treatment
“AESI”	adverse event of special interest, a specific medical event that has been identified before or during a clinical trial as a potential safety concern associated with the medical product being tested
“antibody”	also known as an immunoglobulin, a protein used by the immune system to recognize and bind an antigen
“anti-VEGF”	anti-vascular endothelial growth factor
“ASCO”	American Society of Clinical Oncology, a leading professional organization for physicians and researchers specializing in cancer care and oncology
“autoimmune”	a condition in which the immune system mistakenly attacks the body’s own healthy cells and tissues

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“B cell”	a lymphocyte produced and matured in the bone marrow, and when activated by a specific antigen, they differentiate into plasma cells that secrete antibodies and memory B cells that provide long-lasting immunity
“B7-H3”	anti- B7 homolog 3 protein
“B7-H4”	anti- B7 homolog 4 protein
“BC”	breast cancer
“BLA”	biologics license application
“BsAb”	an antibody that combines two antigen-recognizing elements into a single construct, capable of binding to two different antigens simultaneously
“BTK”	Bruton’s tyrosine kinase
“CAGR”	compound annual growth rate
“CAS score”	clinical activity score, a validated tool used to measure the inflammatory activity of thyroid eye disease
“CD28”	a protein receptor expressed on the T cell surfaces that provides stimulatory signal
“CD276”	also known as anti- B7 homolog 3 protein (B7-H3)
“CD279”	also known as programmed cell death protein 1 (PD-1)
“CDC”	complement-dependent cytotoxicity, a mechanism by which antibodies bound to the surface of a target cell and trigger the classic complement pathway of the immune system
“CDMO”	contract development and manufacturing organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of development and manufacturing services outsourced on a contract basis
“chemotherapy”	a drug treatment that uses cytotoxic chemicals to kill fast-growing cells in a patient’s body. It is most often used as a cancer treatment because cancer cells grow and multiply much faster than most other cells in the body

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“Chronic TED”	chronic thyroid eye disease, a stage that follows the initial active/inflammatory phase
“CI”	confidence interval, a statistical range that is likely to contain the true value of an unknown population parameter with a specified degree of confidence, often 95% or 99%
“clinical trial/study”	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, also commonly referred to as process development, covering the various procedures used to assess the physical and chemical characteristics of drug products, and to ensure their quality and consistency during manufacturing
“c-Met”	a receptor tyrosine kinase encoded by the MET gene
“CO ₂ ”	carbon dioxide
“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
“combination study” or “combination trial”	a clinical trial that tests more than one therapeutic agent or treatment methods
“combination therapy”	a treatment that uses more than one medication or modality
“CR”	complete response, the disappearance of all signs of cancer in response to treatment
“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
“CRPC”	castration-resistant prostate cancer
“CSO”	contract sales organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of services for the development and commercialization of new drugs, medical devices, and other healthcare products
“CTN”	clinical trial notification, a notice to the EMA on clinical study details

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“DAR”	drug-to-antibody ratio, the average number of drug molecules attached to each antibody in an ADC
“DCR”	disease control rate, the total proportion of patients who demonstrate a response to treatment, equal to the sum of complete responses (CR), partial responses (PR) and stable disease (SD)
“DLT”	dose-limiting toxicity, toxicities of a drug or other treatment that are serious enough to prevent an increase in dose or level of that treatment
“DNA”	deoxyribonucleic acid, a molecule that contains genetic instructions
“DOR”	duration of response, the length of time that a tumor continues to respond to treatment without the cancer growing or spreading
“dose escalation study”	a type of study where different doses of an agent (e.g. a drug) are tested against each other to establish which dose works best and/or is least harmful
“dose expansion study”	a type of study that enrolls additional participants to typically further evaluate efficacy, safety, tolerability, pharmacokinetics, and pharmacodynamics
“Dxd”	deruxtecan, a potent topoisomerase I inhibitor used as the cytotoxic payload in benchmark ADCs
“EASI-75”	a clinical efficacy endpoint commonly used in atopic dermatitis, where a patient has achieved at least a 75% improvement from baseline on the Eczema Area and Severity Index
“EGFR-mutant”	cells or tissues harboring mutations in the EGFR gene, which can affect receptor function and are often associated with certain types of cancer
“EOP2 meeting”	end of Phase II meeting, a formal meeting held after Phase II with the regulation authority to conclude Phase II and agree on the Phase III trial design
“ESCC”	esophageal squamous cell carcinoma
“ES-SCLC”	extensive-stage small cell lung cancer, an advanced form of SCLC
“Fc”	crystallizable fragment, which is the tail region of an antibody that interacts with cell surface receptors called Fc receptors and some proteins of the complement system

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“FDA”	the U.S. Food and Drug Administration, responsible for ensuring the safety, efficacy, and quality of drugs, biologics, and medical devices
“first-in-human” or “FIH”	the initial clinical trials conducted in human subjects after preclinical research and animal testing
“first-line” or “1L”	with respect to any disease, the first line treatment refers to the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment. It is also called primary treatment or therapy
“FPI”	first patient in, the date on which the first participant is enrolled into a clinical study
“F-VASI”	facial vitiligo area scoring index, a subset of VASI that focuses on changes in vitiligo affecting the face
“GCP”	good clinical practice, an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans
“GFA”	gross floor area, total area of all floors within a building
“GGFG-Dxd”	GGFG peptide linked to deruxtecan payload
“GGFG-MH toxin”	GGFG peptide linked to our in-house toxin
“GLP”	Good laboratory practice, an internationally recognized standard that governs how non-clinical laboratory studies are designed
“GMP”	the aspects of quality assurance that ensure that medicinal products are consistently produced and controlled to the standards required for their intended use
“HER2-negative” or “HER2-”	HER2 status of tumor cells identified with a test score of IHC 0, IHC 1+ or IHC 2+/ISH-, which can be further classified into HER2-low and HER2-null
“HER2-positive” or “HER2+”	HER2 status of tumor cells identified with a test score of either IHC 3+ or IHC 2+/ISH+
“HR+”	hormone receptor positive
“I/O”	immuno-oncology, a therapeutic approach that harnesses the body’s own immune system to recognize, attack, and eliminate cancer cells
“I/O 1.0”	first generation of immuno-oncology

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“I/O 2.0”	second generation of immuno-oncology
“IC ₅₀ ”	half-maximal inhibitory concentration, a quantitative measure that indicates the drug concentration needed to reduce a biological process by 50% compared to a control
“IFN-γ”	interferon gamma, a cytokine for activation and regulation of the immune system
“IGA-TS”	investigator’s global assessment — treatment success, a clinical endpoint used in atopic dermatitis. It is defined as the proportion of patients achieving an IGA score of 0 (clear skin) or 1 (almost clear skin) with Grade ≥ 2 improvement from baseline
“IGF-1”	insulin-like growth factor 1
“IGF-1R”	insulin-like growth factor 1 receptor
“IGF-2”	insulin-like growth factor 2
“IgG”	immunoglobulin G, the most common type of antibody found in blood circulation that plays an important role in antibody-based immunity against invading pathogens
“IL-6”	interleukin 6, a cytokine produced by various immune and non-immune cells for regulation, inflammation, and hematopoiesis
“IL-8”	interleukin 8, a pro-inflammatory chemokine produced by various immune and non-immune cells for inflammation
“IL-10”	interleukin 10, a regulatory protein produced by immune cells for anti-inflammation
“IL-16”	interleukin 16, an immunomodulatory and pro-inflammatory cytokine produced by various immune and non-immune cells
“ILD”	interstitial lung disease, a disease caused by progressive scarring and inflammation of the lung interstitium
“immunotherapy”	a type of therapy that uses substances to stimulate or suppress the immune system to help the body fight cancer, infection, and other diseases
“ <i>in vitro</i> ”	Latin for “within the glass”, referring to studies that are performed with microorganisms, cells, or biological molecules outside their normal biological context

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“ <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 including animals, humans and plants, as opposed to a partial or dead organism, or those done <i>in vitro</i>
“IND”	investigational new drug, the application for which is the first step in the drug review process by regulatory authorities to decide whether to permit clinical trials
“indication”	a specific condition, disease, or medical purpose for which a drug, treatment, or medical device is intended or approved for use
“IV”	intravenous, administration of medications directly into a vein
“JAK”	Janus kinase family, includes four distinct kinases: JAK1, JAK2, JAK3, and TYK2, all of which play essential and unique roles in immune system function, hematopoiesis, inflammation, and development
“JAKi”	inhibitor of Janus kinase
“LC”	lung cancer
“linker”	one of the three core components of an ADC. A linker connects the antibody and payload via chemical bonds
“LTS”	long-term safety
“mAb” or “monoclonal antibody”	an antibody generated by identical immune cells that are all clones of the same parent cell
“mCRPC”	metastatic castration-resistant prostate cancer
“MOA”	mechanism of action, the specific biochemical process or molecular interaction through which a drug, treatment, or substance produces its intended effect in the body
“metastatic”	in reference to any disease, including cancer, disease producing organisms or 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
“mPFS”	median progression-free survival
“MTD”	maximum tolerated dose, the highest dose of a drug or treatment that does not cause unacceptable side effects

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“NDA”	new drug application
“NDRL”	National Drug Reimbursement List
“NMPA”	the National Medical Products Administration of the PRC (中華人民共和國國家藥品監督管理局)
“NSCLC”	non-small cell lung cancer
“off-target toxicity”	adverse effects that occur when a drug binds to targets other than those for which it was designed to bind
“oncology”	a branch of medicine that deals with tumors, including the study of their development, diagnosis, treatment, and prevention
“ORR”	overall objective response rate, the proportion of patients with a complete response or partial response to treatment
“OS” or “overall survival”	the length of time from either the date of diagnosis or the start of treatment for a disease which patients diagnosed with the disease are still alive. It is used in clinical trials to measure a drug’s effectiveness
“pan-Src”	the broad Src family of tyrosine kinases
“partial response” or “PR”	defined as at least a 30% but less than 100% decrease in the size of a tumor or the extent of cancer in the body in response to treatment, according to RECIST
“payload”	one of the three core components of an ADC. Payloads are conventionally highly active and cytotoxic molecules attached to an antibody via a chemical linker. Noncytotoxic payloads have recently emerged as novel ADC strategies for oncology and non-oncology indications
“PCT”	Patent Cooperation Treaty, an international treaty that allows inventors to seek patent protection for an invention through a single international patent application
“PD-(L)1”	referring to PD-1 or PD-L1
“PD-1”	programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages
“PD-1/VEGF bsAb”	bispecific antibody designed to simultaneously target and block both PD-1 and VEGF

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“PD-L1”	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that binds to its receptor, PD-1, on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
“PD-L2”	PD-1 ligand 2, which is a protein found mainly on activated T cells and other immune cells that binds to its receptor, 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
“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”	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
“Phase I clinical trial”	a study in which a drug is introduced into healthy human participants 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 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 specific targeted disease, and to determine dosage tolerance and optimal dosage
“Phase III clinical trial”	a study in which a drug is administered to an expanded patient population at geographically dispersed clinical trial sites to generate statistically sufficient data to evaluate the efficacy and safety of the drug for regulatory approval and to provide adequate information for the labeling of the product
“PIs”	principal investigators, the qualified healthcare professionals to design, oversee and execute clinical trials
“placebo”	a medical treatment or preparation with no specific pharmacological activity
“PoC”	proof-of-concept

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“preclinical study”	a study 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
“primary endpoint”	the main or most important outcome at the end of a study to assess the effect of the drug being investigated
“progressive disease”	the worsening or growth of tumors, indicating treatment is ineffective
“PSMA”	prostate-specific membrane antigen
“Q2W”, “Q3W” and “Q4W”	dosing frequency referring to “once every two weeks”, “once every three weeks” and “once every four weeks”, respectively
“R&D”	research and development
“RECIST”	Response Evaluation Criteria in Solid Tumors, a set of published rules that define when tumors in cancer patients improve (respond), stay the same (stabilize), or worsen (progress) during treatment with a focus on measuring tumor size and its progress over time to assess treatment effectiveness. The criteria were published in February 2000 by an international collaboration including the European Organization for Research and Treatment of Cancer, National Cancer Institute of the United States, and the National Cancer Institute of Canada Clinical Trials Group, and were subsequently updated in 2009. Now the majority of clinical trials worldwide evaluating cancer treatments for objective response in solid tumors use RECIST
“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. With respect to cancer, the likely relapse occurs because a few of the original cancer cells survived the initial treatment. Sometimes, this is because cancer cells spread to other parts of the body and were too small to be detected during the follow-up immediately after treatment
“RIPK3”	receptor-interacting protein kinase 3
“RP2D”	recommended Phase II dose, the dose of a drug that is chosen to move forward into Phase II clinical trials. It is based on data from Phase I studies, where the primary goal is to evaluate safety, tolerability, pharmacokinetics (PK), and sometimes early signs of efficacy

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“RP3D”	recommended Phase III dose, the dose identified through preceding clinical studies as optimally balancing safety, tolerability, and therapeutic potential, and is therefore selected for confirmatory evaluation of efficacy and safety in Phase III trials
“SAE”	serious adverse event, an adverse event that results in death, or is life-threatening, or requires in-patient hospitalization or causes prolongation of existing hospitalization, or results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect
“SCLC”	small-cell lung cancer
“secondary endpoint”	an additional outcome measure in a clinical trial used to evaluate the effects of a treatment, providing supplementary information on efficacy and safety, such as quality of life or biomarker changes
“second-line” or “2L”	with respect to any disease, the therapy or therapies that are given when initial treatments (first-line therapy) do not work, or stop working
“SMO”	site management organization, a service provider that delivers operational and administrative support to clinical investigators at research sites
“solid tumors”	abnormal masses of tissue that usually do 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, such as carcinomas (cancers starting in epithelial cells) and lymphomas (cancers originating in lymphocytes)
“SS”	safety analysis set, refers to the group of participants who actually receive any amount of the study treatment
“standard of care”	treatment accepted by medical experts as proper for a certain type of disease and widely used by healthcare professionals
“Sub-Q”	subcutaneous injection that delivers drug into the layer of tissue beneath the skin and above the muscle
“T cell”	a lymphocyte produced or processed by the thymus gland, actively participating in the immune response and playing a central role in cell-mediated immunity. T cells are distinguished from other lymphocytes, such as B cells and NK cells, by the presence of a T cell receptor on their surface

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“TAA”	tumor-associated antigen, a molecule that is abnormally or overexpressed on the surface of tumor cells compared to normal tissues
“TEAE”	treatment-emergent adverse event, either an adverse event that starts after the initiation of the study medication or one that existed before study medication but worsened in severity after the initiation of study medication
“TED”	including active TED and chronic TED
“therapeutic window”	the range of drug dosages that can treat disease effectively without having significant toxic effects, or the time interval during which a particular therapy can be given safely and effectively
“TNBC”	triple-negative breast cancer, a subtype of invasive breast cancer that lacks the key receptor and do not respond to hormonal therapies or HER2 treatments
“TNF- α ”	tumor necrosis factor alpha, a key pro-inflammatory cytokine produced mainly by activated immune cells
“Topo I”	topoisomerase I, an enzyme that reduces winding in DNA by breaking and rejoining one or both strands of the DNA molecule
“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
“TROP-2”	trophoblast cell surface antigen 2, a type I transmembrane glycoprotein that is overexpressed in epithelial cancers
“VC period”	vehicle controlled period, a period when the participants receive a treatment that consists only of the inert drug formulation base without active ingredient
“VEGF”	vascular endothelial growth factor, a signal protein that is pivotal in stimulating the growth of new blood vessels and lymphatic vessels
“VEGFR”	vascular endothelial growth factor receptor
“VHH-based antibody”	variable domain of heavy-chain-only antibodies
“VHH-Fc fusion protein”	an antibody that combines the antigen-binding domain of VHH with Fc region
“Vitiligo”	a long-term skin condition in which areas of skin lose their normal pigment because of the attack of immune system on pigment-producing cells
“WCLC”	World Conference on Lung Cancer, an annual conference of International Association for the Study of Lung Cancer