
GLOSSARY OF TECHNICAL TERMS

This glossary contains explanations of certain technical terms used in this document. As such, these terms and their meanings may not correspond to standard industry meanings or usage of these terms.

“ABC”	activated B-cell-like, a subtype of diffuse large B-cell lymphoma (DLBCL) characterized by the activation of specific signaling pathways and a distinct gene expression profile
“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 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
“agonist”	a chemical that binds to and activates a receptor or other protein to produce a biological response
“AS”	ankylosing spondylitis, a kind of chronic inflammatory autoimmune disease primarily affecting the spine and sacroiliac joints, characterized by joint ankylosis, pain, and limited mobility
“ASAS40”	Assessment of Spondyloarthritis International Society 40, defined as an improvement of no less than 40% in at least three of the four domains (same as ASAS20) with an absolute improvement of at least 2 on a 0-to-10 scale, and no worsening in the remaining domain
“ASCT”	autologous stem cell transplantation, a procedure in which a patient’s own hematopoietic stem cells are collected, preserved, and then reinfused after high-dose chemotherapy to restore bone marrow function
“asthma”	a chronic lung disease affecting people of all ages, caused by inflammation and muscle tightening around the airways, which makes it harder to breathe
“atopic dermatitis”	a chronic inflammatory skin condition characterized by dry, itchy, and inflamed skin and associated with a dysregulation of the immune system

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“axSpA”	axial spondyloarthritis, a chronic inflammatory disease primarily affecting the spine and sacroiliac joints, leading to pain and stiffness
“BASDAI”	Bath Ankylosing Spondylitis Disease Activity Index, a self-assessment tool used to measure the severity of symptoms in patients with ankylosing spondylitis
“BC”	breast cancer
“BiADC”	dual-payload ADC, an ADC in which a single antibody is conjugated to two different types of payloads, typically with distinct mechanisms of action and/or physicochemical properties, allowing simultaneous delivery of both drugs to the same target cell
“biosimilar”	a therapeutic biological product that is similar in quality, safety, and efficacy to an approved registered reference product
“BLA”	biologics license application
“BpADC”	biparatopic ADC, an ADC built on a biparatopic antibody designed to bind two distinct epitopes on the same target antigen, thereby enhancing target engagement, receptor internalization and payload delivery
“BTK”	Bruton’s tyrosine kinase, a non-receptor tyrosine kinase that plays a critical role in B-cell receptor signaling, B-cell development, activation, and survival
“bystander effect”	a cytotoxic effect that occurs when the cytotoxic payload from an ADC is released either from the target cell following internalization and degradation of the ADC or after cleavage within the extracellular space, resulting in the payload being taken up by and killing surrounding cells that may or may not express the ADC’s target antigen
“CAGR”	compound annual growth rate
“Category 1”	therapeutic biologics that have not been approved for marketing in the PRC or overseas, as defined under the Provisions on Registration Classification and Declaration Requirements for Biologics (《生物製品註冊分類及申報資料要求》) issued by the NMPA

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“CD20”	cluster of differentiation 20, a kind of transmembrane glycoprotein mainly expressed on the surface of B lymphocytes and involved in regulating the activation, proliferation, and differentiation of B cells
“CDC”	complement-dependent cytotoxicity, an immune mechanism whereby the complement system is activated by antibodies bound to the surface of target cells, such as pathogens or tumor cells. This activation leads to the formation of a membrane attack complex, which creates pores in the target cell membrane and consequently results in cell lysis and death
“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” or “chemo”	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
“CHOP”	a standard first-line chemotherapy regimen used primarily for non-Hodgkin lymphoma (NHL), consisting of cyclophosphamide, hydroxydaunorubicin (doxorubicin), oncovin (vincristine), and prednisone, and commonly used in combination with CD20-targeted monoclonal antibodies to enhance therapeutic efficacy
“CKD”	chronic kidney disease, a progressive condition characterized by a gradual loss of kidney function over time, typically defined by a decrease in the glomerular filtration rate or evidence of kidney damage
“C _{max} ”	maximum plasma concentration, a pharmacokinetic parameter that measures the highest concentration of a drug in the blood, cerebrospinal fluid, or target organ after a dose is given
“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
“CMO”	contract manufacturing organization

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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
“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
“CSCO”	Chinese Society of Clinical Oncology
“CSO”	contract sales organization, a company that provides outsourced sales and marketing services to pharmaceutical, biotechnology, and medical device companies
“cytotoxic”	toxic to living cells
“DAR”	drug-to-antibody ratio, the average number of drug molecules attached to each antibody in an ADC
“DCR”	disease control rate
“DLBCL”	diffuse large B-cell lymphoma, a fast-growing and aggressive type of non-Hodgkin lymphoma that originates from B cells
“DMARD”	disease-modifying antirheumatic drug, a class of drugs used to treat autoimmune diseases like rheumatoid arthritis by modifying the underlying disease process, slowing progression, preventing joint damage, and improving overall function, mainly treats treat autoimmune diseases like rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis
“DMPK”	drug metabolism and pharmacokinetics
“DOR”	duration of response, the length of time that a tumor continues to respond to treatment without the cancer growing or spreading
“EMT”	epithelial-mesenchymal transition, a biological process in which epithelial cells lose their polarity and cell-cell adhesion and acquire mesenchymal characteristics, including enhanced motility and invasiveness

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“FAS”	full analysis set, which refers to the group of subjects that are enrolled and included in the clinical trial analysis, regardless of whether they completed the clinical trial or followed the clinical
“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
“FDA”	the United States Food and Drug Administration, a federal agency of the Department of Health and Human Services
“first-line”	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
“GBM”	glomerular basement membrane, a specialized extracellular matrix layer located between the fenestrated glomerular endothelium and the podocyte foot processes, serving as a key component of the glomerular filtration barrier
“GC” or “glucocorticoid”	steroid hormones produced by the adrenal glands that regulate metabolism, immune response, and stress, and are used to treat conditions like inflammation, allergies, and autoimmune diseases
“GCB”	germinal center B-cell-like, a subtype of diffuse large B-cell lymphoma (DLBCL) that is characterized by gene expression patterns similar to those of normal germinal center B cells. This subtype typically has a better prognosis compared to the activated B-cell-like (ABC) subtype and often responds more favorably to standard chemotherapy treatments
“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 set of principles and guidelines intended to ensure the quality and integrity of non-clinical laboratory studies, primarily used in the testing of chemicals, drugs, and biological products to ensure that studies are conducted in a consistent and reliable manner
“GMP”	good manufacturing practice, a system for ensuring that products are consistently produced and controlled according to quality standards. GMP covers all aspects of production, from raw materials to finished products, ensuring the safety, quality, and efficacy of pharmaceutical products

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“gout”	a metabolic arthritis caused by hyperuricemia, leading to monosodium urate crystal deposition in joints and tissues, triggering acute inflammatory attacks and chronic joint damage
“GQCE”	Consistency of Quality and Efficacy Evaluation for Generic Drugs
“Grade”	term used to refer to the severity of adverse events according to Common Terminology Criteria for Adverse Events (CTCAE) v4.03, using Grade 1, Grade 2, Grade 3, etc.
“gynecological cancer”	a group of malignant tumors that originate in a woman’s reproductive system, including cancer types such as ovarian cancer, cervical cancer and uterine cancer
“head-to-head trial”	a trial designed to evaluate an investigational medicine compared to an existing standard of care
“hematological cancer”	a group of cancers that affect the blood, bone marrow, and lymphatic system, including types such as leukemia, lymphoma, and multiple myeloma
“HER”	human epidermal growth factor receptor, a group of four closely related receptor tyrosine kinases that play important roles in cell growth, survival, and differentiation
“HER2”	human epidermal growth factor receptor 2
“HER2-low”	HER2 status of tumor cells identified with a test score of IHC 1+ or IHC 2+/ISH-
“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”	hazard ratio, a measure used in survival analysis to compare the effect of an explanatory variable on the hazard or risk of an event occurring at a particular point in time between two groups. HR greater than 1 suggests an increased risk of the event occurring in the treatment group compared to the control group, while HR less than 1 indicates a reduced risk
“HR-”	hormone receptor negative
“HR+”	hormone receptor positive

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“HS”	hidradenitis suppurativa, a chronic, recurrent inflammatory skin condition caused by follicular obstruction affecting the pilosebaceous unit, also known as acne inversa
“IBD”	inflammatory bowel disease
“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
“IgG1”	immunoglobulin G1, a subclass of IgG
“IL-4”	interleukin-4, also known as CD124, IL-4R α and BSF receptor, a cytokine produced primarily by immune cells, playing a crucial role in regulating immune responses, particularly in Th2-biased immune responses, alternative macrophage activation, mucosal immunity, allergic inflammation, tumor progression, and atherogenesis
“IL-4R”	interleukin-4 receptor, also known as CD124, IL-4R α and BSF receptor, is a type I cytokine receptor produced by activated Th2 cells and mast cells, playing a critical role in regulating the differentiation and activation of T cells, particularly in promoting the Th2 (T-helper type 2) immune response, alternative macrophage activation, mucosal immunity, allergic inflammation, tumor progression, and atherogenesis
“IL-6”	interleukin-6, a pro-inflammatory cytokine involved in immune activation, antibody production, and inflammatory responses
“IL-13”	interleukin-13, a cytokine primarily produced by immune cells, playing a crucial role in regulating immune responses, particularly in promoting B cell differentiation, class switching to IgE, and driving allergic inflammation
“IL-17”	interleukin-17, a pro-inflammatory cytokine that belongs to the interleukin-17 family, and plays a pivotal role in both innate and adaptive immunity
“IL-17A/F”	two members of the IL-17 cytokine family, produced mainly by T-helper 17 (Th17) cells, and playing a significant role in mediating inflammatory responses and autoimmune diseases
“ImADC”	immune-modulating ADC
“immuno-biologics”	biologic therapies that modulate or harness the body’s immune system to prevent, control, or treat diseases, including cancer and autoimmune disorders

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“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”, studies 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 including animals, humans and plants, 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 the U.S.
“inflammation”	a protective biological response to tissue damage or infection, which serves to destroy, dilute, or wall off both the injurious agent and the injured tissues
“inhibitor”	a chemical or substance added or applied to another substance to slow down a reaction or to prevent an unwanted chemical change
“JAK”	Janus kinases, including Janus kinase 1 or Janus kinase 2 or Janus kinase 3, are a family of intracellular, non-receptor enzymes that transduce cytokine-mediated signals via the JAK-signal transducers and activators of transcription pathway, a key signaling route through which cytokines transduce extracellular signals to induce inflammation, control immune response, and orchestrate hematopoiesis
“KDIGO”	Kidney Disease: Improving Global Outcomes, a non-profit medical organization that aims to enhance the quality of care for individuals with kidney disease
“KOLs”	key opinion leaders, experts and influencers who have significant knowledge in a specific field
“linker”	one of the three core components of an ADC. A linker connects the antibody and payload via chemical bonds
“LIV-1”	also known as SLC39A6 or ZIP6, a zinc transporter of the ZIP family that functions as a multi-pass transmembrane protein
“mAb” or “monoclonal antibody”	an antibody generated by identical immune cells that are all clones of the same parent cell

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“MAC”	membrane attack complex, a structure formed on the surface of pathogen cells, primarily by the complement system, that creates pores in the membrane, leading to cell lysis and death. This complex plays a crucial role in the innate immune response, providing a means for the body to directly eliminate invading microorganisms as part of the first line of defense against infection
“maximum tolerated dose”	the highest dose of a drug or treatment that does not cause unacceptable side effects
“MCL”	mantle cell lymphoma, a type of non-Hodgkin lymphoma that originates from B lymphocytes in the mantle zone of lymph nodes
“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
“methotrexate”	a disease-modifying antirheumatic drug (DMARD) commonly used to treat autoimmune diseases, such as rheumatoid arthritis, psoriasis, and some types of cancer by inhibiting the metabolism of folic acid
“MMAE”	monomethyl auristatin E
“MN”	membranous nephropathy, a kidney disorder caused by autoimmune attack on the glomerular basement membrane
“MNCs”	multinational companies
“MoA”	mechanisms of action
“monosodium urate”	the sodium salt of uric acid that crystallizes in body tissues, particularly in joints, and is mainly responsible for the formation of gout. Elevated levels of MSU can lead to crystal deposition, causing inflammation and pain associated with gout attacks
“monotherapy”	therapy that uses a single drug to treat a disease or condition
“MRCT”	multi-regional clinical trial
“MRI”	magnetic resonance imaging
“natural killer cell”	a type of immune cell that has granules (small particles) with enzymes that can kill tumor cells or cells infected with a virus

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“NDA”	new drug application
“NHL”	non-Hodgkin lymphoma, a group of cancers that originate in lymphocytes, a type of white blood cell, within the lymphatic system. Unlike Hodgkin lymphoma, NHL encompasses many subtypes with varying characteristics and treatment approaches
“nr-axSpA”	non-radiographic axial spondyloarthritis, a kind of subtype of axial spondyloarthritis that primarily involves the spine and sacroiliac joints, presenting with symptoms such as chronic low back pain and morning stiffness, but no definite radiological erosion or ankylosis of the sacroiliac joints is observed on conventional X-rays
“NRDL”	China’s National Reimbursement Drug List
“NSAID”	non-steroidal anti-inflammatory drug,
“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 response rate
“OS”	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
“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. Non-cytotoxic payloads have recently emerged as novel ADC strategies for oncology and non-oncology indications
“PCC”	preclinical candidates
“PCT”	Patent Cooperation Treaty
“PD”	pharmacodynamics, the study of a drug’s molecular, biochemical, and physiologic effects or actions
“PEG”	polyethylene glycol

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“PFS”	progression-free survival, the length of time during and after the treatment that a patient lives without the disease getting worse
“pharmacokinetics” or “PK”	a measurement of how fast and how completely the drug is absorbed into animal or human body, and the distribution, metabolism, and excretion of drugs in animal or human body
“phase 1 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 2 clinical trial”	a study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, preliminarily evaluate the efficacy of the product for specific targeted diseases, and determine dosage tolerance and optimal dosage
“phase 3 clinical trial”	a 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 product’s labeling
“PMN”	primary membranous nephropathy, a kidney disorder characterized by the thickening of the glomerular membrane due to immune complex deposition, often resulting in nephrotic syndrome with symptoms such as proteinuria, edema, and hypertension, and is commonly associated with antibodies against the phospholipase A2 receptor
“PPS”	per-protocol set
“Prostate cancer”	a malignant tumor arising from epithelial cells of the prostate gland and ranks among the most common malignancies in men
“PSA”	prostate-specific antigen, a serine protease produced primarily by epithelial cells of the prostate gland and is widely used as a biomarker for screening, diagnosis, and monitoring of prostate diseases, including prostate cancer

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“psoriasis”	an immune-mediated chronic and recurrent autoimmune disease triggered by the interaction of genetics and environment, where environmental exposures serve as important triggering factors leading to a chronic inflammatory state. Its typical pathological manifestations include the growth of extra blood vessels in the skin and over-rapid replication of skin cells, with characteristic skin lesions as the main clinical presentation
“R&D”	research and development
“RA”	Rheumatoid Arthritis, an autoimmune disease that causes chronic inflammation of the joints and other areas of the body
“ROR1”	receptor tyrosine kinase like orphan receptor 1, a receptor protein that is part of the receptor tyrosine kinase (RTK) family and plays a crucial role in embryonic development and tissue homeostasis, which is expressed in various cancers, including lymphoma and breast cancer
“SAE”	serious adverse event, any medical occurrence in human drug trials that, at any dose, results in death; is life-threatening; requires inpatient hospitalization or prolongs existing hospitalization; results in persistent or significant disability/incapacity; may cause a congenital anomaly/birth defect; or requires intervention to prevent permanent impairment or damage
“SCLC”	small cell lung cancer
“SD”	stable disease
“second-line”	with respect to any disease, the therapy or therapies that are given when initial treatments (first-line therapy) do not work, or stop working
“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)
“standard of care”	treatment accepted by medical experts as proper for a certain type of disease and widely used by healthcare professionals
“STAT”	signal transducers and activators of transcription, a family of proteins that function as transcription factors, mediating the signaling pathways of numerous cytokines and growth factors

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“sUA”	serum uric acid, the concentration of uric acid present in the blood. It is produced as a byproduct of purine metabolism and is normally excreted by the kidneys. Elevated levels of serum uric acid can lead to conditions such as hyperuricemia and gout, while low levels may indicate other health issues
“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
“TCM”	traditional China’s medicine
“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
“therapeutic window”	the range of drug dosages that can treat disease effectively without having toxic effects, or the time interval during which a particular therapy can be given safely and effectively
“third-line”	with respect to any disease, the therapy or therapies that are given when both initial treatment (first-line therapy) and subsequent treatment (second-line therapy) do not work, or stop working
“TNFi”	tumor necrosis factor inhibitors, a class of drugs that block the action of TNF- α , a cytokine involved in systemic inflammation and autoimmune responses. By inhibiting TNF- α , these drugs help reduce inflammation and are commonly used in the treatment of autoimmune diseases such as rheumatoid arthritis, Crohn’s disease, and psoriasis.
“TNF- α ”	tumor necrosis factor-alpha, a cytokine primarily produced by macrophages and T-cells, playing a crucial role in mediating inflammation and the immune response. It is also involved in cell proliferation, differentiation, and apoptosis, and has significant implications in pathological conditions such as autoimmune diseases, chronic inflammatory diseases, and cancer
“topical corticosteroids”	anti-inflammatory medications applied directly to the skin to treat various dermatological conditions, such as eczema, psoriasis, and dermatitis
“TROP2”	human trophoblast cell-surface antigen 2, a transmembrane protein frequently over-expressed in many types of solid tumors

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“ULT”	urate-lowering therapy, treatment aimed at reducing serum uric acid levels to prevent gout attacks and other complications associated with hyperuricemia
“uveitis”	a kind of immune-mediated inflammatory disease involving the uvea (the middle layer of the eye), and often associated with autoimmune diseases such as ankylosing spondylitis and psoriasis, or triggered by factors like infections and trauma
“VBP”	Volume-based Procurement, the centralized drug procurement policy implemented by the Chinese government under which public healthcare institutions purchase pharmaceuticals in bulk through a unified bidding process
“xanthine oxidase inhibitor” or “XO inhibitor”	xanthine oxidase inhibitor, a class of medications that inhibit the enzyme xanthine oxidase, which is crucial in the production of uric acid from purines. By reducing uric acid levels in the blood, these drugs help prevent and treat conditions such as gout and hyperuricemia.