

GLOSSARY OF TECHNICAL TERMS

This glossary of technical terms contains definitions of certain terms used in this document in connection with our Group and our business. The terms and their meanings may not always correspond to standard industry meaning or usage of these terms, and may not be directly comparable to similarly titled terms adopted by other companies operating in the same industries as our Group.

“%AUC _{ex} ”	percentage of AUC _{0-inf} based on extrapolation
“[14C]-ABP-671”	ABP-671 that has been radiolabeled with the carbon-14 (¹⁴ C) isotope, allowing researchers to trace and quantify the drug and its metabolites in the body for absorption, metabolism, excretion, and mass-balance studies
“acute gout flare”	a painful inflammatory arthritis caused by the crystallization of uric acid in joints, typically triggered by hyperuricemia
“add-on”	a drug that is added to a patient’s existing standard treatment to achieve additional benefits. This new therapy augments an established therapy without replacing it. Different from combination therapies which typically refer to starting and using two or more drugs together, an add-on therapy is layered after an initial therapy has already been started
“ADME”	absorption, distribution, metabolism and excretion
“AEs”	adverse events
“AESIs”	adverse events of special interest, which are predefined, medically significant adverse events that are carefully monitored during clinical trials and post-marketing surveillance due to their potential association with a drug’s mechanism, class effects, or known risks
“AFib”	atrial fibrillation
“AKD”	acute kidney disease
“analogue”	a drug compound that is structurally similar to a reference drug but has modified chemical or biological properties
“APIs”	active pharmaceutical ingredients, the biologically active component of a drug product responsible for its therapeutic effect
“ASCVD”	atherosclerotic cardiovascular disease
“AUC”	the area under the concentration curve
“AUC _{0-inf} ”	the area under the concentration curve from time zero to infinity
“AUC _{last} ”	the area under the concentration curve up to the last measurable concentration
“BID”	from Latin “bis in die”, meaning twice a day

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“BLA”	biologics license application
“CAD”	coronary artery disease
“CAGR”	compound annual growth rate
“CBC”	complete blood count, a routine hematological test that evaluates key components of blood, including red blood cells, white blood cells, platelets, hemoglobin, and hematocrit
“CDMO”	contract development and manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing
“CI”	confidence interval, a statistical range that estimates the precision of a clinical or pharmacological measurement with a specified probability that the true value lies within the interval
“CKD”	chronic kidney disease
“CL/F”	apparent clearance of a drug
“C _{max} ”	maximum observed 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
“CMO”	contract manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services for drug manufacturing
“COX-2”	cyclooxygenase-2
“CRO”	contract research organization, an entity that provides outsourced research and development services to pharmaceutical, biotechnology, and medical device industries, supporting clinical trials and related activities
“CRP”	C-reactive protein
“C _{trough} ”	a concentration reached by a drug immediately before the next dose is administered
“CV”	cardiovascular
“CVD”	cardiovascular disease

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“CYP”	cytochrome P450, a family of enzymes primarily found in liver cells that play a crucial role in metabolizing drugs, toxins, and other substances in the body
“DDI”	drug-drug interaction
“ECG”	electrocardiogram; a test that records the electrical activity of heart, including the rate and rhythm
“eGFR”	estimated glomerular filtration rate
“E _{max} ”	maximal drug effect, refers to the peak response achieved by a drug, beyond which increasing the dosage does not result in further effects
“EOP2”	end-of-phase 2, a critical regulatory milestone marking the completion of Phase 2 clinical trials
“FEUa”	fractional excretion of uric acid
“FTD”	fast track designation, a regulatory incentive granted by the FDA to expedite the development and review of drugs that treat serious or life-threatening conditions and address unmet medical needs.
“GI”	gastrointestinal
“GLP-1”	glucagon-like peptide-1; a peptide hormone that decreases blood sugar levels in a glucose-dependent manner by enhancing the secretion of insulin
“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
“gouty arthritis”	an acute inflammatory joint disease caused by the deposition of monosodium urate crystals in synovial fluid and periarticular tissues, resulting from chronic hyperuricemia
“hERG”	refers to the human ether-a-go-go-related gene, which encodes a potassium channel crucial for cardiac repolarization
“HREC”	Human Research Ethics Committee, an independent committee that reviews, approves, and monitors research involving human participants to ensure that it is ethically acceptable, that risks are minimized, and that participants’ rights, safety, and welfare are protected
“hsCRP”	high-sensitivity C-reactive protein, an inflammatory biomarker
“hyperuricemia” or “HUA”	a metabolic condition defined by elevated serum uric acid levels

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“IL-1”	interleukin-1, a master pro-inflammatory cytokine family comprising IL-1 α and IL-1 β
“IL-1 β ”	interleukin-1beta, a potent pro-inflammatory cytokine primarily secreted by activated macrophages and monocytes
“IL-18”	interleukin-18, a pro-inflammatory cytokine that belongs to the interleukin-1 family and plays a key role in innate and adaptive immunity, mainly by inducing interferon- γ production
“IL-6”	interleukin-6, a pleiotropic pro-inflammatory cytokine produced by immune cells
“i.m.”	intramuscular
“ <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.
“inflammasome”	a multiprotein intracellular complex that activates pro-inflammatory cytokines in response to pathogens, cellular damage, or metabolic stress
“KDIGO”	Kidney Disease: Improving Global Outcomes, a non-profit medical organization
“LDL-C”	low-density lipoprotein cholesterol, a type of cholesterol carried by low-density lipoproteins in the blood, high levels of which can lead to plaque buildup in arteries and increase cardiovascular risk
“mAb”	monoclonal antibody
“MAD”	multiple ascending doses, a type of clinical study designed to evaluate a drug after administering multiple doses over a specific period
“MASH”	metabolic dysfunction-associated steatohepatitis, liver inflammation and damage caused by accumulation of fat in the liver
“mITT”	modified intent-to-treat population
“MRCT”	multiregional clinical trial, a globally coordinated clinical study conducted across multiple countries/regions to evaluate a drug’s efficacy, safety, and dosage in diverse populations

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“MTD”	maximum tolerated dose, the highest drug dose that does not cause unacceptable adverse effects in patients or trial subjects
“NAG”	N-acetyl- β -D-glucosaminidase
“NALP3”	NACHT, LRR, and PYD domains-containing protein 3
“NCE”	new chemical entity, a drug that contains an active ingredient that has never before been approved or marketed in any form in the U.S.
“NDA”	new drug application
“nephrolithiasis”	the formation of crystalline calculi (stones) in the kidneys or urinary tract
“NLRP3”	NOD-, LRR- and Pyrin Domain-Containing Protein 3
“NOAEL”	no observed adverse effect level, the highest tested dose of a drug or chemical at which no statistically or biologically significant adverse effects are observed in preclinical studies
“NPC1L1”	Niemann-Pick C1-like 1, an intestinal cholesterol transporter protein responsible for dietary cholesterol absorption
“NSAIDs”	nonsteroidal anti-inflammatory drugs
“OAT4”	organic anion transporter 4
“ODD”	orphan drug designation
“PAD”	peripheral artery disease, circulatory condition characterized by narrowed arteries
“PCSK9”	proprotein convertase subtilisin/kexin Type 9
“PD”	pharmacodynamics, the study of a drug’s molecular, biochemical, and physiologic effects or actions
“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, to preliminarily evaluate the efficacy of the product for specific targeted diseases, and to determine dosage tolerance and optimal dosage

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“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 labeling of the product
“phospholipase A2”	phosphatide 2-acylhydrolase
“PI”	principal investigator, the lead researcher responsible for the design, conduct, and oversight of a clinical trial
“PK”	pharmacokinetics, 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
“placebo”	a medical treatment or preparation with no specific pharmacological activity
“PopPK”	population pharmacokinetic
“pro-inflammatory”	the biological processes that promote inflammation
“QD”	from Latin “quaque die”, meaning once daily
“QQL”	quality of life
“RA _{AUCτ} ”	an observed accumulation ratio based on AUC _τ
“RAC _{max} ”	an observed accumulation ratio based on C _{max}
“rare disease”	a rare disease is defined by FDA as a condition affecting less than 200,000 people
“refractory gout”	a severe, treatment-resistant form of gout characterized by persistent hyperuricemia, chronic tophi, recurrent flares and intolerance to first-line therapies
“s.c.”	subcutaneous
“SAD”	single ascending doses, a clinical trial design used primarily to assess a drug by administering a single dose that gradually increases
“SAEs”	serious adverse events, 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
“SAID”	steroidal anti-inflammatory drug
“SAR”	structure-activity relationship

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“SD”	standard deviation
“sUA”	serum uric acid
“ $t_{1/2}$ ”	half-life, the time required for the concentration to fall to 50% of its peak value
“T2DM”	Type 2 Diabetes Mellitus
“TEAEs”	treatment-emergent adverse event, either an adverse event with onset after the initiation of the study medication or an adverse event with onset before study medication that worsened in severity after the initiation of study medication
“ tE_{max} ”	time taken for a drug to achieve its maximum pharmacological effect (E_{max}) after administration
“ T_{max} ”	time of maximum concentration, the time point after administration of a drug at which the highest concentration of the drug is observed in the bloodstream or target tissue
“TNF- α ”	tumor necrosis factor-alpha, a cytokine that plays a central role in inflammation and immune responses
“tophaceous gout”	a chronic form of gout characterized by the deposition of urate crystal aggregates, called tophi, in joints, soft tissues, or bones
“tophus”	a chronic, granulomatous deposit of monosodium urate crystals in joints, soft tissues, or bones
“TRA”	total radioactivity, the sum of all radio-labeled drug-related material measured in biological samples
“UA”	uric acid, a natural waste product formed from the breakdown of purines, commonly measured in the blood, and elevated levels are closely linked to hyperuricemia and gout
“ULT”	urate-lowering therapy
“URAT1”	urate transporter 1
“urate oxidase” or “uricase”	an enzyme that converts uric acid into a more soluble compound, allantoin, thereby helping the body break down and eliminate excess uric acid
“uric acid episodes”	referred to as gout attacks, are sudden, painful flare-ups caused by a buildup of uric acid in the joints
“VAS”	visual analogue scale

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“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
“ V_d/F ”	apparent volume of distribution
“ V_z/F ”	Apparent volume of distribution during the terminal phase after non-intravenous administration
“XO”	xanthine oxidase
“ λ_z ”	apparent terminal elimination rate constant, represents the fraction of medication eliminated per unit time
“IC ₅₀ ”	half-inhibitory concentration