

GLOSSARY OF TECHNICAL TERMS

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

“Acceptance Notice”	A formal notice from a regulator confirming acceptance of an application for review (e.g., a marketing application).
“acquired resistance”	Resistance developed after exposure to antimicrobials (e.g., via mutation or gene acquisition).
“active comparator” or “active control”	A marketed or standard therapy used as the control arm in a clinical trial (instead of placebo).
“active-controlled study”	A clinical trial that compares an investigational product against an active comparator rather than placebo.
“adverse drug reaction” or “ADR”	An adverse event for which a causal relationship to the drug is at least a reasonable possibility.
“adverse event” or “AE”	Any undesirable medical occurrence in a subject after receiving a drug or undergoing a procedure, whether or not related to the drug.
“alpha-helical (α -Helical)”	A helical peptide/protein secondary structure; alpha-helix formation is often important for membrane interaction by antimicrobial peptides.
“AMP”	Antimicrobial peptide, which is a small protein that defends against bacteria, fungi, and viruses by disrupting microbial membranes or inhibiting essential cellular processes.
“amphipathic”	Having both hydrophobic (lipid-interacting) and hydrophilic (water-interacting) regions, supporting membrane binding and disruption.
“autoimmune disorders”	Diseases driven by immune responses against self-antigens, resulting in chronic inflammation and tissue injury.
“bactericidal”	Capable of killing bacteria (as opposed to merely inhibiting growth).
“bacteriostatic”	Capable of inhibiting bacterial growth without necessarily killing bacteria.
“Barrel-stave Mechanism”	A pore-forming membrane-disruption model where peptides insert into membranes and assemble into transmembrane channels.
“Below the Limit of Quantification” or “BQL”	Drug concentration is below the assay’s quantification limit, indicating very low or undetectable exposure.
“biliary excretion”	Elimination via bile into the gastrointestinal tract; part of ADME assessment.
“biofilm”	A structured microbial community embedded in a protective matrix; often more tolerant to antimicrobial therapy.
“broad-spectrum”	Active against a wide range of pathogens (e.g., Gram-positive and Gram-negative bacteria and/or fungi).

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“buccal Administration”	Delivery via oral mucosa to achieve local action and/or systemic absorption, potentially reducing first-pass metabolism.
“CDE”	The Center for Drug Evaluation of the NMPA (國家藥品監督管理局藥品審評中心), which is the evaluation body under China’s NMPA responsible for technical review of clinical and marketing submissions.
“CDMOs”	Contract development and manufacturing companies, which provide comprehensive development and manufacturing services for drug substances and products on a contract basis.
“cell wall”	The outer structural layer in bacteria/fungi that surrounds the cell membrane and affects permeability and drug access.
“chi-square test”	A statistical test commonly used to compare categorical outcomes between groups.
“clinical endpoint”	A prespecified clinical outcome used to assess treatment effect (e.g., response, healing, infection control).
“clinical response rate”	Proportion of subjects meeting prespecified criteria for clinical response at an assessment timepoint.
“CMC”	CMC stands for Chemistry, Manufacturing, and Controls, refers to the development, production, and quality control of drug substances and drug products.
“colonization”	Presence of microorganisms on/in the body without necessarily causing symptomatic infection.
“comparator”	The control treatment used for comparison (placebo or active comparator).
“conditional approval”	A regulatory pathway where approval may be granted with post-approval obligations, subject to specific conditions.
“crossover administration”	A design where subjects receive more than one treatment (e.g., investigational product and placebo) in different periods.
“CROs”	Contract research organizations, which provide outsourced research support to the pharmaceutical, biotechnology, and medical device industries.
“Current Good Manufacturing Practice” or “cGMP”	Updated GMP requirements applicable at the time of manufacture.
“cytoplasmic membrane”	The lipid bilayer membrane enclosing the cell’s cytoplasm; disruption can cause cell death.
“D-amino acids”	Amino acids in D-configuration; incorporation may enhance protease resistance and improve peptide stability.
“diabetic foot infection” or “DFI”	Infection associated with diabetic foot complications; commonly involves mixed microbial infections and may include MDR pathogens.
“dose escalation” or “dose-ascending”	Stepwise increase of dose across cohorts to evaluate safety, tolerability and exposure.
“Dose Group”	A cohort of subjects assigned to receive a specific dose level.

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“double-blind”	Both subjects and investigators are unaware of treatment assignment to reduce bias.
“dysphagia”	Difficulty swallowing; may occur in oropharyngeal infections and can affect nutrition and quality of life.
“E3 ligase”	An enzyme complex involved in ubiquitination; recruited by degraders to tag target proteins for degradation.
“electrostatic interaction”	Attraction between opposite electrical charges (e.g., cationic peptides and anionic microbial membranes).
“End-of-Phase II Meeting” or “EOP2”	A regulator interaction to discuss Phase II data and align on pivotal Phase III design and strategy.
“eradication rate”	Proportion of subjects achieving elimination of a pathogen at a defined timepoint based on microbiological assessments.
“eukaryotic cells”	Cells with a nucleus (e.g., human cells); membrane composition differs from prokaryotic cells.
“every 8 hours” or “q8h”	Dosing frequency meaning every 8 hours, typically three times daily.
“FGF19”	Fibroblast growth factor 19, an endocrine hormone involved in bile acid and metabolic regulation.
“FGF21”	Fibroblast growth factor 21, an endocrine hormone involved in energy and metabolic regulation.
“first-in-class” or “FIC”	A “first-in-class” drug is broadly defined as a therapeutic agent that introduces a completely novel mechanism of action into clinical practice.
“Food and Drug Administration” or “FDA”	U.S. authority overseeing clinical trials and marketing authorisations for drugs and biologics.
“full analysis set” or “FAS”	Main efficacy analysis population, generally aligned with intent-to-treat principles per protocol definition.
“fungal cell membrane”	The lipid bilayer of fungal cells; disruption can lead to antifungal effects.
“fungicidal”	Capable of killing fungi.
“genotoxicity”	The potential of a substance to damage genetic material; evaluated in non-clinical safety testing.
“GFA”	Gross floor area
“Good Laboratory Practice” or “GLP”	Quality system for non-clinical studies ensuring data integrity, traceability and reliability.
“Good Manufacturing Practice” or “GMP”	Quality standards governing manufacturing to ensure consistent product quality and compliance.
“Gram-negative bacteria”	Bacteria with an outer membrane and thinner peptidoglycan layer; often harder to treat due to permeability barriers.
“Gram-positive bacteria”	Bacteria with thick peptidoglycan and no outer membrane; includes common pathogens.
“hematologic malignancy”	Malignancies arising from blood-forming tissues and lymphoid lineages (e.g., leukemias, lymphomas, myeloma).

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“hydrophilic face”	The polar surface of an amphipathic helix that interacts with aqueous environments or polar head groups.
“hydrophobic face”	The non-polar surface of an amphipathic helix that interacts with lipid membrane cores.
“hydrophobic interaction”	Interaction between non-polar groups and lipid components that promotes membrane insertion/disruption.
“immunocompromised”	Having reduced immune function, increasing susceptibility to opportunistic infections.
“ <i>in vitro</i> ”	Experiments performed outside a living organism (e.g., assays in plates or tubes).
“ <i>in vivo</i> ”	Experiments conducted in living organisms (animals or humans).
“inhalation”	Delivery to the respiratory tract via inhaled formulations; can provide local pulmonary exposure and/or systemic absorption.
“International Nonproprietary Name” or “INN”	WHO-assigned generic name for a pharmaceutical substance, intended to be globally recognised and non-proprietary.
“International Working Group on the Diabetic Foot” or “IWGDF”	A global expert group that issues guidance and classification systems for diabetic foot disease and infection.
“Investigational New Drug” or “IND”	Regulatory submission to initiate clinical trials; in the U.S., IND clearance generally allows a trial to proceed.
“IWGDF Grade II”	IWGDF is a grading category used to describe the severity of diabetic foot ulcer infection in certain clinical contexts, and Grade II generally refers to an infected diabetic foot ulcer limited to the skin and subcutaneous tissue, without involvement of deeper structures (e.g., fascia, muscle, tendon, joint or bone) and without systemic features.
“KIF18A”	Kinesin family member 18A, a microtubule-based motor protein involved in regulating chromosome alignment during mitosis.
“KRAS”	Kirsten rat sarcoma viral oncogene homolog, a small GTPase that regulates cell growth and survival signaling and is frequently mutated in human cancers.
“lipid bilayer”	Double layer of lipids forming cell membranes; disruption compromises membrane integrity and cell viability.
“liquid chromatography-tandem mass spectrometry” or “LC-MS/MS”	Analytical method used to quantify drug concentrations in biological matrices.
“local administration”	Delivery at the site of disease (e.g., topical or mucosal), intended to limit systemic exposure.
“lower limit of quantification” or “LLOQ”	The lowest concentration that can be quantitatively measured with acceptable accuracy and precision.
“Membrane Discrimination Mechanism”	Selective interaction with microbial membranes (typically more negatively charged) over mammalian membranes (near-neutral), leading to preferential pathogen membrane disruption.

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“metabolic dysfunction-associated steatohepatitis” or “MASH”	Inflammatory form of metabolic fatty liver disease that can progress to fibrosis or cirrhosis.
“methicillin-resistant <i>staphylococcus aureus</i> ” or “MRSA”	A drug-resistant strain of <i>S. aureus</i> resistant to methicillin and many related antibiotics.
“MIC range”	Range of MIC values across isolates; used to characterise variability in potency.
“MIC90”	Concentration inhibiting 90% of tested isolates; summary measure for antimicrobial activity.
“microbiological response rate”	Proportion achieving prespecified microbiological outcome (e.g., eradication) at a timepoint.
“minimum inhibitory concentration” or “MIC”	Lowest concentration of an antimicrobial that inhibits visible growth of a microorganism.
“mixed infection”	Infection involving more than one pathogen (e.g., bacterial plus fungal coinfection).
“modified full analysis set” or “mFAS”	A protocol-defined modification of the FAS with additional inclusion/exclusion rules for analysis.
“multicenter”	Conducted at multiple clinical trial sites, improving generalisability and recruitment.
“multidrug-resistant” or “MDR”	Resistant to multiple antimicrobial classes, limiting treatment options.
“National Medical Products Administration” or “NMPA”	China’s national authority regulating drugs and medical products, including clinical trial and marketing review.
“nephrotoxicity”	Kidney toxicity; a safety risk associated with certain antimicrobials.
“neurotoxicity”	Nervous system toxicity; a safety risk associated with certain antimicrobials.
“New Delhi metallo-β-lactamase-1” or “NDM-1”	A resistance factor associated with broad beta-lactam antibiotic resistance; linked to difficult-to-treat infections.
“New Drug Application” or “NDA”	Regulatory submission seeking marketing approval, supported by non-clinical, clinical, and CMC data.
“no observed adverse effect level” or “NOAEL”	Highest tested dose at which no adverse effects are observed in non-clinical studies.
“obesity”	A chronic metabolic disease characterised by excess adiposity and associated metabolic comorbidities.
“open-label”	Treatment assignments are known to subjects and investigators.
“oral mucosa”	Tissue lining the mouth; a site for local drug delivery and absorption.
“oropharyngeal candidiasis”, or “OPC”, or oral candidiasis	Fungal infection involving the oropharynx (commonly <i>Candida spp.</i>), often in immunocompromised populations. In routine practice, the boundary between OPC and oral candidiasis is often blurred, and the terms are used in a non-differentiated manner.

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“outer membrane”	An additional membrane layer in Gram-negative bacteria that can impede drug penetration.
“P value”	Probability measure used in hypothesis testing; smaller values indicate stronger evidence against the null hypothesis.
“parallel development”	Conducting development activities in more than one jurisdiction concurrently.
“PARP-1”	PARP-1 refers to poly(ADP-ribose) polymerase 1, a nuclear enzyme involved in DNA damage detection and repair by catalyzing poly(ADP-ribosyl)ation of target proteins.
“pharmacodynamics” or “PD”	Relationship between drug exposure and biological effect, including mechanism and magnitude of response.
“pharmacokinetic set” or “PKS”	Analysis population used for pharmacokinetic assessment based on protocol-defined criteria.
“pharmacokinetics” or “PK”	Drug absorption, distribution, metabolism and excretion over time; often measured via plasma concentrations.
“phosphatidylcholine” or “PC”	A major zwitterionic phospholipid in mammalian membranes, contributing to near-neutral surface charge.
“phosphatidylethanolamine” or “PE”	A zwitterionic phospholipid commonly found in mammalian membranes, contributing to near-neutral surface charge.
“phosphatidylglycerol” or “PG”	An anionic phospholipid enriched in bacterial membranes, contributing to negative surface charge.
“phosphatidylserine” or “PS”	An anionic phospholipid referenced as enriched in microbial membranes in the document context.
“pivotal study”	A confirmatory trial intended to provide primary evidence supporting marketing authorisation.
“placebo”	An inactive control treatment used to assess treatment effect versus no active therapy.
“placebo-controlled”	A design comparing an investigational product versus placebo to estimate treatment effect and safety.
“plasma protein binding”	Degree to which a drug binds plasma proteins; high binding can affect free drug exposure and distribution.
“post-antifungal effect”	Sustained suppression of fungal growth after limited exposure to an antifungal agent.
“pre-NDA meeting”	Regulatory interaction held before NDA submission to align on requirements and readiness.
“preferred term” or “PT”	Standardised adverse event terminology classification used in safety reporting.
“prokaryotic cells”	Cells without a nucleus (e.g., bacteria); membrane composition differs from eukaryotic cells.
“protease degradation”	Breakdown of peptides by proteases; an important stability consideration for peptide therapeutics.
“protease-resistant”	Resistant to enzymatic degradation by proteases, often improving peptide stability in biological environments.

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“protein–protein interaction” or “PPI”	Physical interaction between proteins; often challenging to drug with conventional small-molecule inhibitors.
“proteolysis-targeting chimera” or “PROTAC”	A bifunctional molecule that recruits an E3 ligase to a target protein, inducing ubiquitination and proteasomal degradation.
“pulmonary infection”	Infection involving the lungs/respiratory tract; may be a target indication for inhaled or systemic anti-infective therapies.
“random coil”	A relatively unstructured peptide conformation in solution; may transition to alpha-helix upon membrane contact.
“randomized”	Subjects are assigned to treatment groups by chance to reduce selection bias.
“resistance-induction experiment”	Experimental assessment of whether repeated exposure leads to emergence of reduced susceptibility/resistance.
“safety set” or “SS”	Analysis population used for safety summaries, typically including all subjects who received at least one dose.
“secondary wound infection”	Microbial infection occurring in pre-existing acute or chronic wounds, which may delay healing and lead to complications.
“secondary infection of burn wounds”	secondary infections of first-degree or superficial second-degree burn and scald wounds caused by <i>Staphylococcus epidermidis</i> , <i>Staphylococcus haemolyticus</i> , or <i>Acinetobacter baumannii</i> .
“sepsis”	Life-threatening organ dysfunction due to dysregulated host response to infection.
“serious adverse event” or “SAE”	Event resulting in death, life-threatening outcome, hospitalisation/prolongation, significant disability, or other medically significant event.
“single ascending dose” or “SAD”	Design assessing safety and PK after a single dose across escalating dose cohorts.
“single-center”	Conducted at one clinical site; often used in early-phase studies.
“SMOs”	Site management organizations, which provide site-level support such as patient recruitment, coordinator management and protocol compliance to improve trial efficiency and quality.
“solid tumor”	A non-hematologic malignancy forming a mass lesion, distinct from blood cancers.
“statistical significance”	A result unlikely to have occurred by chance under a prespecified threshold.
“study may proceed” or “SMP”	Regulatory status indicating authorisation to initiate clinical trials under the applicable framework.
“suppository”	Solid dosage form inserted into a body cavity where it dissolves/melts to deliver drug locally and/or systemically.
“systemic circulation”	Blood circulation throughout the body; systemic exposure refers to drug presence in this circulation.

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“systemic exposure”	The extent to which a drug enters systemic circulation; assessed by plasma concentrations and PK parameters.
“systemic infection”	Infection disseminated via the bloodstream and/or affecting multiple organs; typically associated with higher clinical severity.
“targeted protein degradation” or “TPD”	A therapeutic approach that reduces disease-related proteins by inducing their degradation rather than inhibiting their activity.
“thermosensitive gel”	Formulation that changes physical state with temperature to enhance local retention at body temperature.
“topical”	Applied directly to a body surface (e.g., skin/mucosa) for local effect.
“Toxicokinetics” or “TK”	The study of the absorption, distribution, metabolism and excretion (ADME) of a test article in toxicology studies, typically used to characterize systemic exposure (e.g., C _{max} , AUC) and support interpretation of toxicity findings and exposure margins.
“transmembrane aqueous pore”	A water-filled channel formed in a membrane, enabling leakage of cellular contents and loss of membrane integrity.
“treatment-emergent adverse event” or “TEAE”	Any AE that begins or worsens after initiation of study treatment.
“treatment-related adverse event” or “TRAE”	An AE assessed as related, possibly related, or reasonably related to the study treatment.
“TYK2”	Tyrosine kinase 2, a Janus kinase family member that mediates cytokine receptor signaling and downstream JAK-STAT pathway activation.
“ulcerative colitis” or “UC”	Chronic inflammatory bowel disease of the colon with relapsing-remitting mucosal inflammation.
“urinary excretion”	Elimination of drug-related material via urine; part of ADME assessment.
“vaginitis”	Inflammation/infection of the vagina due to bacterial and/or fungal pathogens; may include single-pathogen and mixed-infection settings.
“vulvovaginal candidiasis” or “VVC”	Vaginal yeast infection, commonly caused by <i>Candida</i> species, associated with pruritus, discharge and irritation.
“zwitterionic phospholipid”	A phospholipid with both positive and negative charges but net neutral; common in mammalian membranes (e.g., PC, PE).