
GLOSSARY OF TECHNICAL TERMS

This glossary contains definitions of certain technical terms used in this document in connection with us and our business. These may not correspond to standard industry definitions and may not be comparable to similarly terms adopted by other companies.

“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
“ALP”	alkaline phosphatase, an enzyme primarily found in the liver, bones, intestine, and kidneys, and a key biomarker indicating the presence of cholestatic liver diseases including primary sclerosing cholangitis and primary biliary cholangitis
“ALT”	alanine aminotransferase, an enzyme found in the liver that helps convert proteins into energy for the liver cells, the level of which indicates liver damage, making it a biomarker commonly associated with injury or apoptosis of liver cells
“Amylin”	also known as islet amyloid polypeptide (IAPP), a 37-amino acid peptide hormone co-secreted with insulin from pancreatic β -cells in response to nutrient intake, which plays a role in glucose homeostasis by slowing gastric emptying, suppressing postprandial glucagon secretion, and regulating food intake and satiety through centrally-mediated mechanisms
“AST”	aspartate aminotransferase, an enzyme found in the liver, heart, muscles and kidneys, high levels of which in the blood indicates hepatitis, cirrhosis, or other liver diseases
“AUC”	area under curve, a parameter of systemic exposure
“AUC _{0-t} ”	the area under the drug concentration-time curve from time zero to the last measured time point, it is an indicator of drug absorption and exposure over a specific period of time
“AUC _{0-∞} ”	the area under the drug concentration-time curve from time zero to time infinity, it is an indicator of drug exposure
“ β -cell” or “pancreatic β -cell”	a type of endocrine cell in the pancreas that produces insulin
“ β -oxidation”	beta oxidation, the process by which mitochondria break down fatty acid molecules
“BMI”	body mass index, a numerical value calculated from height and weight, providing a standardized measure to classify individuals as underweight, healthy weight, overweight, and obesity
“BTD”	breakthrough therapy designation, a process designed to expedite the development and review of drugs that are intended to treat a serious condition
“C _{max} ”	the maximum observed concentration of a drug in a specified compartment or test area of the body

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“CAGR”	compound annual growth rate
“CDE”	the Center for Drug Evaluation of the NMPA
“CMC”	chemistry, manufacturing, and controls, a term for the chemical composition, formulation, and quality control processes used in the manufacturing of a drug
“Combo” or “Combination therapy”	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 research services to pharmaceutical and biotechnology companies on a contract basis
“CSO”	contract sales organization, a company that provides outsourced sales and marketing services to another company on a contractual basis
“CVD”	cardiovascular disease, a broad term referring to a group of disorders affecting the heart and blood vessels, including coronary heart disease, cerebrovascular disease (such as stroke), peripheral arterial disease, rheumatic heart disease, congenital heart disease, and other conditions
“diabetic nephropathy”	a serious complication of diabetes, also known as diabetic kidney disease, characterized by progressive kidney damage caused by high blood sugar levels damaging the blood vessels in the kidneys, leading to albuminuria, hypertension, and potential progression to end-stage renal disease
“DILI”	drug-induced liver injury
“double-blind”	a type of clinical trial in which neither the participants nor the researcher knows which treatment or intervention participants are receiving until the clinical trial is completed
“dual agonist”	a therapeutic agent designed to activate two distinct biological targets or pathways simultaneously
“ECG”	electrocardiogram; a test that records the electrical activity of the heart, including the rate and rhythm
“Exenatide”	a GLP-1 receptor agonist and the first drug in the incretin mimetic class, approved by the FDA as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, which works by increasing glucose-dependent insulin secretion from pancreatic beta cells, suppressing glucagon secretion, delaying gastric emptying, and reducing food intake
“FDA”	the United States Food and Drug Administration
“FGF21”	fibroblast growth factor 21, an endogenous metabolic hormone predominantly produced by the liver that governs systemic energy homeostasis and lipid metabolism, which exerts pleiotropic effects including improvement of dyslipidemia through reduction of triglycerides and LDL cholesterol and increase of HDL cholesterol, reduction of liver fat, resolution MASH and improvement of liver fibrosis, as well as favorable effects on insulin-related markers

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“FTD”	fast track designation, a designation granted by the FDA of a drug for expedited review to facilitate the development of drugs which treat serious or life-threatening condition or fill an unmet medical need
“GGT”	gamma-glutamyl transferase, an enzyme found primarily in the liver; the level of GGT increases when the liver is damaged, making it a biomarker commonly associated with injury or apoptosis of liver cells
“GIAE”	Gastrointestinal adverse events, common side effects of certain medications, especially GLP-1 receptor agonists, and include nausea, vomiting, diarrhea, constipation, and more serious complications like pancreatitis or gastroparesis
“GIPR”	glucose-dependent insulintropic polypeptide receptor, the receptor for glucose-dependent insulintropic polypeptide, a 42-amino acid peptide secreted by enteroendocrine ‘K-cells’ found primarily in the proximal intestine
“GLP-1”	glucagon-like peptide-1, a peptide hormone that exerts biological function through activation of GLP-1 receptors, is expressed in various organs and tissues in the body, including adipose tissue, the liver, the cardiovascular system, and the central nervous system. In pancreatic islets, GLP-1 stimulates insulin secretion and suppresses glucagon release. Importantly, GLP-1 can increase β -cell regeneration. Furthermore, GLP-1 can also suppress appetite, delay gastric emptying, regulate blood lipid metabolism and reduce fat deposition.
“GLP-1 receptor agonist” or “GLP-1RA”	a class of drug that activates the GLP-1 receptor for the treatment of diabetes, obesity/overweight, nonalcoholic steatohepatitis and other metabolic diseases
“glucagon”	a hormone that raises blood sugar levels by signaling the liver to release stored glucose
“glucagon receptor” or “GCGR”	a protein that is activated by glucagon that is a target of interest for developing innovative drugs for the treatment of diabetes
“half-life”	the time required for a quantity of substance to reduce to half of its initial quantity
“HbA _{1c} ”	hemoglobin A1C, a blood test that measure an individual’s glucose control levels
“HDL-C”	high-density lipoprotein cholesterol, often referred to as “good” cholesterol as it is known to remove other forms of cholesterol from the bloodstream
“HFD”	high-fat diet, a diet consisting of at least 35% of total calories is consumed from fats, both unsaturated and saturated
“HoFH”	homozygous familial hypercholesterolemia
“ <i>in vitro</i> ”	Latin for “within the glass”, referring to studies that are performed with biological molecules outside their normal biological context
“ <i>in vivo</i> ”	Latin for “within the living”, referring to studies in which the effects of various biological molecules are tested on whole, living organisms or cells, usually animals, including humans, and plants, as opposed to a tissue extract or dead organism

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“IND”	investigational new drug, an application in the drug review process required by a regulatory authority to decide whether a new drug is permitted to initiate clinical trials
“insulin”	a hormone that regulates blood glucose levels by facilitating the uptake of glucose from blood into cells and inhibiting the liver from producing more glucose
“LDL-C”	low-density lipoprotein cholesterol, often referred to as “bad” cholesterol as it may build up in the walls of blood vessels and cause atherosclerotic diseases
“LFC”	liver fat content, the percentage of fat in liver cells
“liver fibrosis”	the excessive accumulation of extracellular matrix proteins including collagen that occurs in most types of chronic liver diseases
“MAD”	multiple ascending dose, a clinical trial design in which drug doses are gradually increased to determine the tolerability and optimal dose of the study drug after multiple dosing
“MAFLD”	metabolic dysfunction-associated fatty liver disease, a novel concept proposed in 2020 aiming to replace the term NAFLD, defined as hepatic steatosis in the presence of overweight or obesity, type 2 diabetes mellitus, or evidence of metabolic dysregulation, which does not require the exclusion of other etiologies of liver disease such as excessive alcohol consumption or viral hepatitis, thereby allowing for the inclusion of mixed etiologies
“MASH”	metabolic dysfunction-associated steatohepatitis (formerly known as nonalcoholic steatohepatitis or NASH), an advanced form of MASLD
“metabolic disease”	a kind of disorder that disrupts normal metabolism, the body’s natural process of converting food into nutrients on a cellular level
“MNC”	multinational companies
“Mono” or “monotherapy”	the use of a single therapy
“NMPA”	the National Medical Products Administration of the PRC (國家藥品監督管理局)
“NRDL”	the National Reimbursement Drug List, a list that names all the drugs covered by the medical insurance program in full or partially in China
“obesity”	the abnormal or excessive fat accumulation in the body, defined as an individual having a body mass index over 28kg/m ² or more in China and 30 kg/m ² or more in the United States
“ODD”	orphan drug designation, a designation granted by the FDA to a drug or biological product which prevents, diagnoses or treats a rare disease or condition, qualifying the sponsors for certain incentives
“off-label”	related to the use of pharmaceutical drugs for an unapproved indication or in an unapproved age group, dosage or route of administration

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“onset”	the amount of time it takes for a drug to start producing its therapeutic effects after administration
“open-label”	a type of clinical trial in which information is not withheld from trial participants
“OSA”	obstructive sleep apnea syndrome, a sleep disorder characterized by recurrent episodes of partial or complete upper airway obstruction during sleep, leading to reduced or paused breathing (apneas or hypopneas), often accompanied by oxygen desaturation and fragmented sleep
“overweight”	a term used to refer to an excess body weight relative to height, typically defined by a body mass index of 24 kg/m ² to 28 kg/m ² in China and 25 kg/m ² to 30 kg/m ² in the United States
“PCT”	Patent Cooperation Treaty, an international patent law treaty that provides a unified procedure for filing patent applications in its contracting states
“PD”	pharmacodynamics, the study of how a drug affects an organism, which, together with pharmacokinetics, influences dosing, benefit, and adverse effects of the drug
“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
“placebo”	a medical treatment or preparation with no specific pharmacological activity
“QA”	quality assurance, the systematic efforts taken to assure that a drug meets with all the quality expectations
“QC”	a process by which a company reviews the quality of all factors involved in the production of a drug
“SAD”	single ascending dose, a study design in which single doses of a drug are gradually increased to evaluate safety and tolerability
“SAE”	the serious adverse medical event that results in death, is life-threatening, causes permanent or significant disability, requires hospitalization or extends hospital stays
“SHTG”	severe hypertriglyceridemia, a metabolic condition characterized by severely elevated levels of triglycerides in the blood (typically ≥500 mg/dL), which is associated with substantial morbidity and an increased risk of acute pancreatitis
“SMO”	site management organization, an organization that provides clinical trial related services to the investigator at clinical site for medical device companies having adequate infrastructure and staff to meet the requirements of the clinical trial protocol
“t _{1/2} ”	terminal half life
“T _{max} ”	the time taken to reach the maximum observed concentration of a drug

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“T2D”	type 2 diabetes mellitus, a form of diabetes characterized by high blood sugar, insulin resistance and relative lack of insulin; the pancreas in T2DM patient makes less insulin, and the body becomes resistant to insulin
“TEAE”	the adverse medical event occurring during the treatment period
“THR- β ”	thyroid hormone receptor β , one receptor for thyroid hormone to mediate the biological activities of thyroid hormone
“titration”	the process of adjusting the dose of a medication for the maximum benefit without adverse effects
“triglycerides” or “TG”	the most common type of fat in the human body. Triglycerides in the blood are associated with an increased risk of cardiovascular disease and pancreatitis