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.

"505(b)(1)"	a new drug application filed pursuant to Section 505(b)(1) of the U.S. Federal Food, Drug, and Cosmetic Act, which requires the applicant to submit full reports of investigations of safety and effectiveness, in addition to other information required by the FDA. The data contained in the application must either be owned by the applicant or the applicant must have obtained the right of reference to such data
"505(j)"	an abbreviated new drug application filed pursuant to Section 505(j) of the U.S. Federal Food, Drug, and Cosmetic Act, which requires the applicant to demonstrate that the proposed drug product is identical or has the same active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics and intended use as a previously approved reference listed drug
"acylation"	a process in which an acyl group is added into a compound
"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
"ANDA"	Abbreviated New Drug Application, application for the approval of a generic version of an already approved brand-name drug
"API"	active pharmaceutical ingredient, the biologically active component in a pharmaceutical drug that produces the intended therapeutic effect
"ARDS"	acute respiratory distress syndrome, a life-threatening lung condition that occurs when fluid builds up in the alveoli (air sacs) of the lungs, preventing adequate oxygen from reaching the bloodstream. It is characterized by rapid onset of widespread inflammation in the lungs
"Article 10(1)"	a generic drug application filed pursuant to Article 10(1) of Directive 2001/83/EC of the European Parliament and of the Council in the European Union. Under this pathway, the applicant for marketing authorization is not required to provide the results of non-clinical tests and clinical trials if the applicant can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorized under Article 6 of Directive 2001/83/EC for not less than eight years in any member state of the European Union or in the European Union
"bioavailability"	the proportion of a drug that enters the systemic circulation when introduced into the body and is available for therapeutic action. High bioavailability indicates that a drug is effectively absorbed and utilized by the body, which is crucial for the efficacy of inhalation therapies
"BLA"	biologics license application

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"CAGR"	compound annual growth rate
"Category 1 Biologics"	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
"Category 1 Chemical Drug"	an innovative drug that has not been approved for marketing in the PRC or overseas, containing new chemical compounds with well-defined structures, pharmacological effects and clinical value, as defined under the Provisions on Registration Classification and Declaration Requirements for Chemical Drugs (《化學藥品註冊分類及申報資料要求》) issued by the NMPA
"Category 2 Chemical Drug"	a modified new drug that has not been approved for marketing in the PRC or overseas, which is optimized on the basis of known active ingredients in terms of structure, dosage form, formulation and manufacturing process, route of administration or indications, and demonstrates significant clinical advantages, as defined under the Provisions on Registration Classification and Declaration Requirements for Chemical Drugs (《化學藥品註冊分類及申報資料要求》) issued by the NMPA
"Category 3 Chemical Drug"	a generic drug manufactured by domestic applicants in the PRC, for which the corresponding reference listed drug has been approved for marketing overseas but not in the PRC. Such generic drug shall be demonstrated to be therapeutically equivalent to the reference listed drug in terms of quality and efficacy, as defined under the Provisions on Registration Classification and Declaration Requirements for Chemical Drugs (《化學藥品註冊分類及申報資料要求》) issued by the NMPA
"Category 4 Chemical Drug"	a generic drug manufactured by domestic applicants in the PRC, for which the corresponding reference listed drug has been approved for marketing in the PRC. Such generic drug shall be demonstrated to be therapeutically equivalent to the reference listed drug in terms of quality and efficacy, as defined under the Provisions on Registration Classification and Declaration Requirements for Chemical Drugs (《化學藥品註冊分類及申報資料要求》) issued by the NMPA
"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
"cGMP"	current good manufacturing practice, guidelines that assure proper design, monitoring, and control of drug manufacturing process
"C_{max}"	the maximum observed concentration of a drug, a pharmacokinetic parameter that measures the highest concentration of a drug in the blood, cerebrospinal fluid, or target organ after a dose is given

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"CMC"	chemistry, manufacturing and controls, also commonly referred to as process development, which covers the comprehensive documentation and processes that define the chemical composition, manufacturing procedures, and quality control measures for pharmaceutical products. CMC encompasses the development, scale-up, and validation of manufacturing methods to ensure consistent product quality and compliance with regulatory standards
"CNS"	central nervous system, comprises the brain and spinal cord
"combination therapy"	a treatment approach that uses multiple methods or drugs simultaneously
"COPD"	chronic obstructive pulmonary disease, a chronic inflammatory lung disease that causes obstructed airflow from the lungs, with symptoms including breathing difficulty, cough and mucus production
"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
"DMF"	Drug Master File, a confidential document submitted to regulatory agencies containing detailed information about facilities, processes, or materials used in the manufacturing, processing, and packaging of a drug
"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
"DPI"	dry powder inhaler, a type of inhalation device that delivers medication to the lungs in the form of a dry powder. DPIs do not require propellants and rely on the patient's inhalation effort to disperse the powder into respirable particles
"EC_{50}"	half maximal effective concentration, referring to the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum after a specified exposure time
"EMA"	the European Medicines Agency, responsible for the scientific evaluation, supervision, and safety monitoring of medicines within the EU and the European Economic Area
"excipients"	inactive substances formulated alongside the API in a drug product, which play various roles, including aiding the manufacturing process, enhancing drug stability, and improving the delivery and absorption of the active ingredient
"FDA"	the United States Food and Drug Administration, a federal agency of the Department of Health and Human Services
"gastrointestinal"	the digestive system that includes the mouth, throat, esophagus, stomach, small intestine, large intestine and rectum

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"GCP"	good clinical practice, an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans
"GIP"	glucose-dependent insulinotropic polypeptide, an inhibiting hormone of the secretin family of hormones
"GLP-1"	glucagon-like peptide-1, a peptide hormone that exerts biological function through activation of GLP-1receptors, which are expressing 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 cell regeneration. Furthermore, GLP-1 based therapy can also suppress appetite, delay gastric emptying, regulate blood lipid metabolism and reduce fat deposition
"half-life"	the time required for a quantity of substance to reduce to half of its initial quantity
"HbA1c"	Hemoglobin A1c, a measure of blood sugar level
"hypoglycemia"	a medical condition characterized by an abnormally low level of glucose (sugar) in the blood, often resulting in symptoms such as shakiness, sweating, confusion, and in severe cases, unconsciousness or seizures
"ICS"	inhaled corticosteroids, a form of inhaled steroid medication primarily used to reduce inflammation in the airways, controlling and preventing asthma and COPD symptoms. ICS are typically used as long-term maintenance therapy to help patients reduce the frequency and severity of acute exacerbations
"*in vitro*"	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
"*in vivo*"	Latin for "within the living", studies *in vivo* 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 *in vitro*
"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China or the U.S.
"innovative drug"	Category 1 innovative drug or Category 2 modified new drug as classified by the NMPA in China, and comparable designations in other jurisdictions
"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

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"KOL"	key opinion leader, expert or influencer who has significant knowledge in a specific field
"LABA"	long-acting β2-adrenergic receptor agonist, a class of bronchodilators that provide sustained bronchodilation by stimulating β2-adrenergic receptors in the airway smooth muscles. Commonly used in combination with ICS to enhance therapeutic effects and reduce the risk of asthma exacerbations
"LAMA"	long-acting anticholinergic bronchodilator, a class of bronchodilators that provide sustained bronchodilation by blocking muscarinic receptors in airway smooth muscles. Used as maintenance therapy in COPD and severe asthma
"MASH"	metabolic dysfunction-associated steatohepatitis, the liver manifestation of a metabolic disorder, and the most severe form of non-alcoholic fatty liver disease, previously known as non-alcoholic steatohepatitis (NASH)
"MDI"	metered dose inhaler, a handheld device that delivers a specific amount of medication to the lungs in the form of a short burst of aerosolized medicine. MDI typically uses a propellant to create the aerosol and require coordination between actuation and inhalation by the patient
"metabolic disease"	a kind of disorder that disrupts normal metabolism, the body's natural process of converting food into nutrients on a cellular level
"monotherapy"	therapy that uses a single drug to treat a disease or condition
"NDA"	new drug application
"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"	a condition that refers to the abnormal or excessive fat accumulation in the body
"oncology"	a branch of medicine that deals with tumors, including the study of their development, diagnosis, treatment, and prevention
"overweight"	a condition that refers to an excess body weight relative to height
"PCC"	preclinical candidate compound, a drug candidate that has completed initial laboratory testing and is ready for preclinical studies to evaluate safety and efficacy
"pharmacodynamics" or "PD"	the study of a drug's molecular, biochemical, and physiologic effects or actions

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"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
"placebo"	an inactive substance, treatment, or procedure designed to look and be administered exactly like the active experimental treatment but without any therapeutic value
"SMI"	soft mist inhaler, an advanced inhalation device designed to deliver medication in a gentle, slow-moving mist form. Unlike traditional pressurized MDIs, SMIs do not use propellants
"T2DM"	type 2 diabetes, 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
"TSLP"	thymic stromal lymphopoietin, a cytokine that plays a key role across the spectrum of asthma inflammation
"VBP"	volume-based procurement, a set of drug procurement regulations implemented in China with the goal of promoting generic substitutes and lowering the price of medications that have outlived their exclusivity periods
"WHO"	World Health Organization, a specialized agency of the United Nations that aims to promote global health, coordinate international health efforts, and address public health challenges worldwide