

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 similar terms adopted by other companies.

“AD”	atopic dermatitis, a chronic, relapsing, inflammatory skin disease characterized clinically by pruritus, polymorphic skin lesions with exudative tendencies
“ADME”	absorption, distribution, metabolism and excretion
“AE”	adverse event, any untoward medical occurrences in a patient or clinical investigation subject administered a drug or other pharmaceutical product during clinical trials and which do not necessarily have a causal relationship with the treatment
“AESI”	adverse event of special interest
“ANDA”	abbreviated new drug application
“AR”	allergic rhinitis, a non-infectious chronic inflammatory disease of the nasal mucosa mainly mediated by immunoglobulin E (IgE) when atopic individuals are exposed to allergens
“BID”	<i>bis in die</i> , which means twice a day
“BSA”	body surface area
“CADD”	computer-aided drug design
“CDE”	Center for Drug Evaluation of the NMPA
“CDMO”	contract development and manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis, providing drug development and drug manufacturing services
“cGMP”	current Good Manufacturing Practice
“clinical trial”	an experiment performed on human beings in order to evaluate the comparative efficacy of two or more therapies. An experimental design used for testing the effectiveness of a new medication or a new therapeutic procedure. Individuals are usually assigned randomly to a treatment group (experimental therapy) and a control group (placebo or standard therapy) and the outcomes of the two groups are compared
“CMO”	Contract Manufacturing Organization

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“C _{max} ”	the maximum (or peak) serum concentration that a drug achieves in a specified compartment or test area of the body after the drug has been administered and before the administration of a second dose
“CMC”	chemistry, manufacturing, and controls, a term for the chemical composition, formulation, and quality control processes used in the manufacturing of a drug
“CRO”	contract research organization, a company that provides research services to pharmaceutical and biotechnology companies on a contract basis
“CSO”	contract sales organization, a third-party company that provides sales services to pharmaceutical, biotechnology, and medical device companies
“EASI”	eczema area and severity index, a clinical measure used to evaluate the effectiveness of treatments for atopic dermatitis. It is a score calculated based on the severity of lesions in different areas of the skin, the size of the affected areas, and a composite score that incorporates the area of each body part in relation to the total body surface area
“FAS”	full analysis set
“FDA”	the United States Food and Drug Administration, a federal agency of the Department of Health and Human Services
“glaucoma”	a degenerative eye disease characterized by elevated intraocular pressure and damage to the optic nerve
“GMP”	Good Manufacturing Practice, a system for ensuring that products are consistently produced and controlled according to quality standards, which is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. It is also the practice required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of pharmaceutical products
“hyperkeratosis”	the thickening of the outer layer of the skin that contains a tough, protective protein called keratin
“IGA”	Investigator’s Global Assessment score, an assessment of skin conditions, particularly atopic dermatitis and psoriasis, based on the physician’s subjective judgment, allowing researchers to quickly evaluate the severity of the disease at a given time point. It is commonly used to assess drug efficacy

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“IgE”	immunoglobulin E, a type of antibody which plays a key role in the body’s defense against certain infections and is also involved in allergic reactions. When an allergen enters the body, IgE antibodies bind to it and trigger the release of histamine and other chemicals from mast cells and basophils, leading to symptoms such as itching, swelling, and redness. Elevated levels of IgE are often associated with allergic conditions
“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
“inhibitor”	a substance that binds to and decreases the activity of a specific enzyme or protein, thereby regulating biological processes and often used therapeutically to block disease-related pathways
“innovative drug”	drugs with original structures or novel mechanisms of action
“IL-4”	interleukin-4, a cytokine that regulates immune cell function
“IL-13”	interleukin-13, an immunoregulatory cytokine secreted predominantly by activated Th2 cells and mast cells
“ <i>in vitro</i> ”	Latin for “within the glass”, studies using components of an organism that has been isolated from their usual biological surroundings
“IOP”	intraocular pressure, the fluid pressure of the eye
“iTNSS”	instantaneous total nasal symptom score
“iTOSS”	instantaneous total ocular symptom score
“IVPT”	<i>in vitro</i> permeation test, the test that estimates the degree to which a dosage form promotes or inhibits the permeation of its ingredients across physiological barrier
“IVRT”	<i>in vitro</i> release test, an <i>in vitro</i> release testing parameter which determines release of drug from the topical dosage form
“JAK”	Janus kinase, a family of intracellular, non-receptor tyrosine kinases that transduce cytokine-mediated signals via the JAK-STAT pathway
“JAK inhibitor”	small molecules targeting Janus kinase (JAK) enzymes (JAK1/2/3, TYK2) to block cytokine signaling via the JAK-STAT pathway

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“JAK-STAT signaling pathway”	a cytokine-stimulated signal transduction pathway that is involved in numerous critical biological processes, including cell proliferation, differentiation, apoptosis and immune regulation. It can regulate the final expression of genes, cell proliferation, differentiation and immune response
“locally-delivered targeted therapy”	a type of treatment that is directed to a specific organ or limited area of the body to specifically target molecules and pathogenic mechanisms
“Membranous Nephropathy”	a pathological and morphological diagnostic term characterized by the deposition of immune complexes in the lateral aspect of the glomerular basement membrane and subepithelial region, accompanied by diffuse thickening of the glomerular basement membrane and changes in the permeability of the glomerular filtration membrane
“MRGPRX2”	mas-related G-protein coupled receptor member X2, a promiscuous receptor on mast cells that mediates IgE-independent degranulation in response to many structurally diverse compounds and has been implicated in multiple mast cell-mediated disorders, including chronic urticaria and atopic dermatitis
“NDA”	new drug application
“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
“NSV”	non-segmental vitiligo, a depigmented skin disorder showing progressive and depigmented lesions of the skin, mucosa, and hair
“Olmsted syndrome” or “OS”	a rare hereditary keratinization disorder primarily caused by autosomal dominant mutations in the TRPV3 gene, clinically characterized primarily by severe palmoplantar keratoderma and hyperkeratotic plaques around body orifices, including the perioral, periocular and perigenital regions
“PAR”	perennial allergic rhinitis
“Phase I clinical trial”	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

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“Phase II clinical trial”	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
“Phase III clinical trial”	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
“PK”	pharmacokinetics, the study of the absorption, distribution, metabolism and excretion of drugs in the body, which, together with pharmacodynamics, influences dosing, benefit and adverse effects of the drug
“placebo”	any dummy medical treatment; originally, a medicinal preparation having no specific pharmacological activity against the patient’s illness or complaint given solely for the psychophysiological effects of the treatment; more recently, a dummy treatment administered to the control group in a controlled clinical trial in order that the specific and non-specific effects of the experimental treatment can be distinguished
“PN”	prurigo nodularis, a chronic inflammatory skin disease characterized by severe pruritus, nodules, papules, excoriations and ulceration
“pruritus”	the symptom of itchiness in the skin, which is one of the most common clinical symptoms associated with dermatological conditions such as atopic dermatitis, psoriasis, xerosis, prurigo nodularis, contact dermatitis, urticaria, and eczema
“QD”	<i>quaque die</i> , which means once a day
“ROCK”	Rho-associated coiled-coil containing protein kinase, a crucial enzyme family that acts as a major downstream target of the RhoA protein, regulating the cell’s actin cytoskeleton to control cell shape, movement, division, and survival, playing vital roles in processes like cancer, fibrosis, and neurological pain, and making it a significant therapeutic target
“rTNSS”	reflective total nasal symptom score, a rating of the severity of nasal symptoms over certain period of time
“rTOSS”	reflective total ocular symptom score, a rating of the severity of ocular symptoms over certain period of time

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“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 causes prolongation of existing hospitalization; results in persistent or significant disability/incapacity; may have caused a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage
“SAR”	seasonal allergic rhinitis
“SERPINE1”	Serpin Family E Member 1
“SMO”	site management organization, an organization that has adequate infrastructure and staff to meet the requirements of the clinical trial protocol and provides clinical trial related services to a CRO, a pharmaceutical company, a biotechnology company, or a clinical site
“TEAE”	treatment-emergent adverse event, any adverse event that occurs or worsens in severity after a patient begins receiving a treatment or intervention in a clinical trial
“Th2 cells”	T helper 2 cells, an important subset of helper T cells, involved in humoral immunity and allergic reactions. It plays a core role in amplifying and maintaining inflammatory responses marked by eosinophil recruitment and mast cell activation
“Tmax”	time to achieve maximum drug concentration, the time it takes for a drug to reach the maximum concentration (Cmax) after administration of a drug that needs to be absorbed
“TRPV3”	transient receptor potential vanilloid 3, a temperature-sensitive transient receptor potential ion channel that functions as a Ca ²⁺ -permeable non-selective cation channel, activated by warm temperatures and various compounds, and is expressed in both neuronal and non-neuronal tissues