GLOSSARY OF TECHNICAL TERMS

This glossary of technical terms 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.

"AD"	Atopic dermatitis
"AE"	Adverse events
"AS"	Ankylosing Spondylitis
"API"	Active Pharmaceutical Ingredient, the biologically active component in a pharmaceutical drug that produces the intended therapeutic effects. APIs are the primary substances responsible for the efficacy of medications
"AUC"	area under the curve
"BD"	Behçet's Disease, also known as Behçet's syndrome, is a chronic, recurrent, systemic vasculitis that can affect multiple organs and systems, including the skin, mucous membranes, eyes, joints, gastrointestinal tract, and central nervous system
"BID"	Bis in Die (Latin for "twice a day"), a medical abbreviation indicating that a medication or treatment should be administered two times per day, typically spaced 12 hours apart
"BSA change rate"	the percentage change in Body Surface Area, or BSA, affected by a condition (e.g., psoriasis) or involved in a specific measurement, usually over a given period of time
"chemical therapy"	a type of treatment that involves the use of chemically synthesized small-molecule compounds to target specific biological pathways
"CMC"	Chemistry, Manufacturing and Controls refer to the regulatory and scientific framework governing the development, production, and quality assurance of pharmaceutical products. It encompasses the processes and documentation related to the composition, manufacturing methods, stability, and quality control of drug substances and drug products
"CMO"	contract manufacturing organization
"COPD"	chronic obstructive pulmonary disease
"CRO"	contract research organization

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"CSCO Guidelines"	Chinese Society of Clinical Oncology Guidelines, The CSCO guidelines refer to the clinical practice guidelines developed and published by the Chinese Society of Clinical Oncology (CSCO). CSCO is a leading professional organization in China dedicated to the advancement of oncology research, education, and clinical practice. The CSCO guidelines provide evidence-based recommendations for the diagnosis, treatment, and management of various types of cancers, tailored to the specific clinical and regulatory environment in China. These guidelines are widely recognized and adopted by healthcare professionals and institutions across China, and they play a significant role in standardizing oncology care, informing clinical decision-making, and guiding the design and conduct of clinical trials within the region
"CBR"	Clinical Benefit Rate, a measure used in clinical trials to represent the proportion of patients who achieve a predefined clinical benefit, such as complete response, partial response, or stable disease, for a specified duration
"DLQI"	a widely used questionnaire designed to measure the impact of skin diseases on a patient's quality of life. It is commonly used in dermatology clinical trials and routine practice to assess how much a skin condition (e.g., psoriasis, eczema, acne) affects a patient's daily life, emotions, and social interactions
"DMARDs"	Disease-Modifying Antirheumatic Drugs, a group of drugs designed to slow or alter the progression of autoimmune diseases such as rheumatoid arthritis and psoriatic arthritis. DMARDs work by suppressing the immune system to prevent joint and tissue damage. Examples include methotrexate, sulfasalazine, and leflunomide
"EGFR"	or Epidermal Growth Factor Receptor, is a transmembrane protein that belongs to the receptor tyrosine kinase family. It plays a critical role in regulating cell growth, survival, proliferation, and differentiation. EGFR is activated by binding to specific ligands such as epidermal growth factor (EGF), leading to the activation of downstream signaling pathways involved in cellular processes. Mutations or overexpression of EGFR have been implicated in the development and progression of various cancers, making it a key therapeutic target in oncology
"endpoint"	with respect to a clinical study or trial, the outcome that is measured, whether referring to occurrence of disease, symptom, sign or laboratory abnormality constituting a target outcome, in which case "endpoint" will be preceded by the outcome term, such as in "clinical remission endpoint" or "maintenance therapy endpoint"
"FAS"	Full Analysis Set

"GCP Inspections"	GCP inspections refer to regulatory audits conducted by health authorities to assess compliance with Good Clinical Practice (GCP) standards during the conduct of clinical trials. GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials that involve human subjects. The primary objectives of GCP inspections are to ensure the rights, safety, and well-being of trial participants are protected, and to verify the integrity and reliability of clinical trial data. Regulatory agencies such as the NMPA in China, among others, routinely perform GCP inspections at clinical trial sites, sponsor facilities, and CROs. Findings from GCP inspections can impact the approval and acceptance of clinical trial data for regulatory submissions
"HADS"	Hospital Anxiety and Depression Scale, a validated questionnaire used to assess levels of anxiety and depression in patients, commonly utilized in hospital and clinical research settings
"HER2"	HER2, or human epidermal growth factor receptor 2 (also known as ERBB2), is a member of the same receptor tyrosine kinase family as EGFR. HER2 is involved in the regulation of cell growth and differentiation. Overexpression or amplification of the HER2 gene is associated with aggressive forms of certain cancers, particularly breast cancer and gastric cancer. Targeting HER2 with specific therapies has become an important strategy in the treatment of HER2-positive malignancies
"IBD"	inflammatory bowel disease, including Crohn's disease and UC
"IBDQ Scores"	The Inflammatory Bowel Disease Questionnaire (IBDQ) scores are patient-reported outcome measures used to assess health-related quality of life in individuals with IBD, such as CD and UC. The IBDQ consists of a series of questions that evaluate multiple domains, including bowel symptoms, systemic symptoms, emotional function, and social function. Patients rate the severity or frequency of symptoms and their impact on daily life, resulting in a composite score that reflects the overall burden of disease. IBDQ scores are widely used in clinical trials and routine practice to monitor disease activity, evaluate treatment efficacy, and support clinical decision-making. The IBDQ is recognized as a validated and reliable tool for measuring quality of life outcomes in patients with inflammatory bowel disease
"IDMC"	Independent Data Monitoring Committee
"IKK"	IKK, or IκB kinase, is a protein complex that plays a central role in the regulation of the nuclear factor kappa-light-chain-enhancer of activated B cells (NF-κB) signaling pathway. The IKK complex phosphorylates the inhibitor of NF-κB (IκB), leading to its degradation and subsequent activation of NF-κB, which translocates to the nucleus to regulate the expression of genes involved in inflammation, immune responses, cell proliferation, and survival. Dysregulation of the IKK/NF-κB pathway has been implicated in a variety of diseases, including cancer, autoimmune disorders, and chronic inflammatory conditions

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"IND"	Investigational New Drug, the authorization granted by a regulatory agency (such as the NMPA) to allow a new drug candidate to be tested in humans during clinical trials
"JAK"	janus kinase inhibitors
"LTBI"	latent tuberculosis infection
"MDHAQ"	The Multi-Dimensional Health Assessment Questionnaire or MDHAQ, score is a patient-reported outcome measure designed to assess the overall health status, functional ability, and quality of life in individuals with rheumatic diseases, such as rheumatoid arthritis. The MDHAQ includes multiple domains, such as physical function, pain, fatigue, and psychological well-being, and provides a composite score that reflects the patient's perception of their disease impact. The MDHAQ score is widely used in clinical practice and research to monitor disease progression, evaluate treatment effectiveness, and facilitate patient-physician communication. It is recognized as a validated and efficient tool for routine assessment in rheumatology
"mPRS"	Modified Partial Response Score, a clinical assessment tool used to evaluate the degree of partial response to treatment, often in oncology studies; specific criteria may vary depending on disease context
"NDA"	New Drug Application
"NMPA"	National Medical Products Administration of China
"NSAIDs"	Nonsteroidal Anti-Inflammatory Drugs, a class of medications that reduce inflammation, pain, and fever by inhibiting enzymes involved in the inflammatory process. Common examples include ibuprofen and naproxen. NSAIDs are often used to manage mild symptoms in conditions like arthritis and psoriasis
"ORR"	objective response rate a clinical trial endpoint that represents the proportion of patients whose cancer shrinks (partial response) or disappears (complete response) after treatment. It is commonly used to assess the effectiveness of anticancer therapies and includes both complete and partial responses as defined in the clinical trial design
"RA"	Rheumatoid Arthritis, an autoimmune disease that causes chronic inflammation of the joints and other areas of the body. This creates inflammation that causes the tissue that lines the inside of joints (the synovium) to thicken, resulting in swelling and pain in and around the joints
"PASI"	Psoriasis Area and Severity Index

"PDE4"	PDE4, or phosphodiesterase 4, is an enzyme belonging to the phosphodiesterase family that specifically hydrolyzes cyclic adenosine monophosphate (cAMP) into its inactive form. By regulating intracellular levels of cAMP, PDE4 plays a key role in controlling inflammatory and immune responses, as well as various cellular signaling pathways. Inhibition of PDE4 has been shown to have anti-inflammatory effects and is a therapeutic strategy for treating certain inflammatory diseases, including COPD, psoriasis, and AD
"PDE4B"	PDE4B is an enzyme belonging to the PDE4 family. It specifically hydrolyzes cAMP into its inactive form, thereby regulating intracellular levels of cAMP. PDE4B is expressed in various tissues, particularly in immune cells and the central nervous system, and plays an important role in modulating inflammatory responses, immune cell activity, and certain neurological processes. Dysregulation of PDE4B has been associated with inflammatory diseases, psychiatric disorders, and some cancers, making it a target for therapeutic intervention.
"PDX model"	A Patient-Derived Xenograft (PDX) model is an in vivo preclinical research model in which diseased tissue, such as tumor and Ps skin tissue, obtained directly from a patient are implanted into immunodeficient mice or other suitable animal hosts. PDX models closely recapitulate the histological, genetic, and biological characteristics of the original patient tumor, including its heterogeneity and response to therapeutics. These models are widely used in oncology research to evaluate the efficacy and safety of investigational drugs, to study mechanisms of drug resistance, and to facilitate personalized medicine approaches. PDX models are considered a valuable tool for bridging the gap between in vitro studies and clinical trials, providing more predictive insights into clinical outcomes
"PFS"	progression-free survival, a clinical trial endpoint that measures the length of time during and after treatment in which a patient lives with a disease (such as cancer) without it worsening or progressing. PFS is used to evaluate the effectiveness of a therapy in delaying disease advancement
"pharmacodynamics"	the study of the biochemical and physiologic effects of drugs (especially pharmaceutical drugs). The effects can include those manifested within animals (including humans), microorganisms, or combinations of organisms (for example, infection)
"pharmacokinetics" or "PK"	a branch of pharmacology dedicated to determining the fate of substances administered to a living organism
"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
"PI"	Principal investigators
"placebo"	a substance or treatment with no active therapeutic effect, commonly used in clinical trials as the administered substance for the control group
"PPK"	population pharmacokinetic
"PPS"	Per Protocol Set
"primary endpoint"	with respect to a clinical study or trial, the main predefined result that is measured at the end of a study (e.g., the number of deaths or the difference in survival between the treatment group and the control group)
"Ps"	Psoriasis is a chronic, immune-mediated inflammatory skin disease characterised by recurrent episodes of erythematous, scaly plaques
"PsA"	Psoriatic Arthritis
"QD"	once a day
"R&D"	research and development
"SAEs"	Serious adverse events
"secondary endpoint"	with respect to a clinical study or trial, a secondary objective that was measured. For example, a drug designed to prevent allergy-related deaths might also have a measure of whether quality of life is improved
"sPGA score"	Static Physician's Global Assessment Score. It is a clinical tool used to assess the severity of psoriasis based on the physician's evaluation of the overall appearance of a patient's skin lesions at a specific point in time (static, not dynamic).
"TEAE"	treatment-emergent adverse event, an AE that emerges during treatment having been absent pre-treatment, or worsens relative to the pre-treatment state