

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 directly comparable to similarly titled terms adopted by other companies.

“5-HT”	serotonin, also known as 5-hydroxytryptamine, is a monoamine neurotransmitter
“Acceptance Notice”	an official notice issued by the CDE of NMPA confirming the acceptance of an IND application. The Acceptance Notice shall specify that if a clinical trial applicant does not receive any negative or questioning opinions from the CDE within 60 days from the date of acceptance of the application and payment of fees, the applicant may conduct the clinical trial in accordance with the trial protocol submitted to the CDE
“AD”	atopic dermatitis, a chronic, relapsing inflammatory skin disease characterized by immune dysregulation, skin barrier dysfunction, pruritus and eczematous lesions
“advanced solid tumors”	solid tumors that are locally advanced, metastatic or otherwise not amenable to curative local treatment
“AE”	adverse event, any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product, which does not necessarily have a causal relationship with such treatment
“AKK”	<i>Akkermansia muciniphila</i> , a gut-associated bacterial species that has attracted research and product development interest for its potential role in maintaining gut barrier function, supporting metabolic balance and regulating immune homeostasis
“anti-PD-1/L1 monoclonal antibody”	a monoclonal antibody targeting the PD-1/PD-L1 immune checkpoint pathway, used in cancer immunotherapy to help restore anti-tumor immune responses
“apoptosis”	a form of programmed cell death in which cells are eliminated in a regulated manner without causing significant inflammation
“AR”	allergic rhinitis, an allergic inflammatory condition affecting the nasal passages
“B16F10”	a highly metastatic murine melanoma cell line
“ <i>Bacteroides fragilis</i> ”	an anaerobic, Gram-negative, rod-shaped bacterium that is part of the normal microbiota of the human colon
“BALB/c”	a commonly used laboratory mouse strain with a stable genetic background, frequently used in immunology, inflammation and allergy studies
“BAX”	BCL2-associated X protein, a pro-apoptotic protein that promotes programmed cell death

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“BCL2”	B-cell lymphoma 2, an anti-apoptotic protein that promotes cell survival by inhibiting programmed cell death
“ <i>Bifidobacterium</i> ”	A genus of gram-positive, anaerobic bacteria naturally present in the human gut and commonly used as a traditional probiotic ingredient
“biological product”	a pharmaceutical product manufactured from or using biological materials or biological processes, including products derived from microorganisms
“BMI”	body mass index, a measure of body weight relative to height
“Bristol Stool Form Scale”	a scale used to classify stool form and consistency, commonly used in gastrointestinal clinical studies
“C57BL/6”	a commonly used laboratory mouse strain with a stable genetic background, frequently used in preclinical disease models across immunology, oncology and metabolic research
“CD8+ T cell”	a type of cytotoxic T lymphocyte that can kill infected cells, including virus-infected cells, and cancer cells
“CDMO”	contract development and manufacturing organization, a company that provides drug development and manufacturing services to pharmaceutical companies on a contract basis
“CFU”	colony forming unit, a unit used to estimate the number of viable bacterial or fungal cells in a sample
“cGMP”	current Good Manufacturing Practice, the current Good Manufacturing Practice regulations and standards enforced by regulatory authorities to ensure that pharmaceutical products are consistently produced and controlled according to up-to-date quality standards appropriate to their intended use
“CID”	chemotherapy-induced diarrhea, diarrhea occurring as a complication of chemotherapy, which can affect treatment tolerance and patient outcomes
“CMC”	chemistry, manufacturing and controls, refers to the chemistry, manufacturing process and quality control information relating to a drug or biological product, including, among others, its composition, manufacturing process, specifications, analytical methods, stability, packaging and storage conditions, which is submitted to regulatory authorities to support the quality, safety and efficacy of such product
“CPT-11”	CPT-11 is irinotecan, one of the chemotherapy drugs most commonly associated with CID

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“CRO”	contract research organization, a third-party service provider that supports research and development activities, including clinical development activities such as project management, clinical monitoring, data management, statistical analysis, medical writing and pharmacovigilance
“CSO”	contract sales organization, a third-party company that provides sales and marketing services to pharmaceutical companies
“CSR”	clinical study report, a document describing the design, conduct, statistical analysis and results of a clinical trial
“CT26”	a mouse colon cancer cell line widely used in biomedical research
“CTCAE”	Common Terminology Criteria for Adverse Events, a standardized classification and severity grading system developed by the U.S. National Cancer Institute and widely used in clinical trials
“cytokine”	a signaling protein released by cells that helps regulate immune and inflammatory responses
“dendritic cells”	antigen-presenting immune cells that help initiate and regulate immune responses
“DNBS”	2, 4-dinitrobenzenesulfonic acid, a chemical used to induce experimental colitis in preclinical animal models
“double-blind”	a clinical trial design in which both subjects and investigators are generally unaware of the assigned treatment group
“DSS”	dextran sulfate sodium, a chemical used to induce experimental colitis in preclinical animal models
“ECG”	electrocardiogram, a test that records the electrical activity of the heart
“endpoint”	a pre-defined outcome measure used to evaluate the efficacy or safety of a treatment in a clinical trial
“FAS”	full analysis set, an analysis population used for efficacy analyses in a clinical trial, generally including all randomized or enrolled subjects who receive at least one dose of the investigational product and have evaluable efficacy data, as specified in the statistical analysis plan
“FITC”	fluorescein isothiocyanate, a widely used fluorescent label for tagging biomolecules, including for visualizing the distribution of test articles in preclinical studies
“Foxp3+ T cell”	a T cell expressing forkhead box P3, the master transcription factor and lineage-defining marker of regulatory T cells

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“FPI”	first patient in, the date on which the first subject is enrolled in a clinical trial
“GCP”	Good Clinical Practice, an ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials involving human subjects
“GMP”	Good Manufacturing Practice, regulations and standards that provide systems to assure proper design, monitoring and control of manufacturing processes and facilities
“gut microbiota dysbiosis”	an imbalance in the composition or function of gut microorganisms
“H22”	a mouse ascites-type hepatocellular carcinoma cell line
“IBS”	irritable bowel syndrome, a common functional gastrointestinal disorder affecting the digestive system, which may cause abdominal pain, bloating and altered bowel habits including diarrhea or constipation
“IBS-D”	diarrhea-predominant IBS, a major subtype of IBS characterized by recurrent abdominal pain associated with predominantly loose or watery stools, urgency and other bowel-related symptoms
“IFN- β ”	interferon beta, an immune molecule involved in antiviral responses
“IFN- γ ”	interferon gamma, an immune molecule involved in antiviral and immune responses
“IL-10”	interleukin-10, an anti-inflammatory cytokine involved in regulating immune responses and maintaining immune homeostasis
“IL-11”	interleukin-11, a cytokine in the IL-6 family
“IL-1 β ”	interleukin-1 beta, a pro-inflammatory cytokine involved in inflammatory and immune responses
“IL-22”	interleukin-22, a cytokine involved in mucosal barrier function, tissue repair and intestinal epithelial regeneration
“IL-4”	Interleukin-4, a vital cytokine produced by the immune system that promotes T helper 2 immune responses
“IL-6”	interleukin-6, a cytokine involved in inflammatory, immune and metabolic responses
“IL-7”	interleukin-7, a cytokine involved in T-cell development, survival and immune homeostasis
“IL-8”	interleukin-8, a pro-inflammatory chemokine involved in neutrophil recruitment and inflammatory responses

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“ILC3”	group 3 innate lymphoid cells, immune cells involved in mucosal immunity and intestinal homeostasis
“immune checkpoint inhibitor”	a cancer immunotherapy that targets immune checkpoint pathways to help restore anti-tumor immune responses
“ <i>in vivo</i> ”	in a living organism, typically referring to studies or experiments conducted in animals or humans rather than in cells or test tubes
“IND”	investigational new drug, a regulatory application submitted to the relevant authority to permit a drug candidate to be studied in human clinical trials, subject to applicable regulatory requirements
“intestinal barrier”	the protective physical and functional barrier of the intestinal lining that helps regulate absorption and limit entry of harmful substances
“intestinal permeability”	the extent to which substances can pass through the intestinal lining
“ <i>Lactobacillus</i> ”	A genus of gram-positive, lactic acid—producing bacteria widely used as a traditional probiotic ingredient in food and supplement products
“LBP” (collectively, “LBPs”)	live biotherapeutic products, are typically live microbial preparations composed of living microorganisms. However, in recent years, the LBP industry has gradually evolved beyond live microorganisms toward broader therapeutic modalities, including inactivated microbial products
“LSLV”	last subject last visit, the date on which the last subject enrolled in a clinical trial completes the final protocol-specified visit or procedure, and is commonly used to refer to the operational completion of the clinical trial
“lyophilization”	freeze-drying, a dehydration process used to improve product stability by removing water under low temperature and vacuum conditions
“MA104 cells”	a cell line used in virology research, including assays involving rotavirus
“MAD”	multiple ascending dose, a Phase I clinical trial design where subjects receive multiple doses of a drug at ascending dose levels to assess safety and tolerability upon repeated dosing
“microbiome”	the community of microorganisms, including bacteria, fungi and viruses, and their genetic material in a particular environment
“MUC2”	mucin 2, a major component of the intestinal mucus layer, secreted primarily by goblet cells
“MyD88”	myeloid differentiation primary response 88, an adaptor protein involved in inflammatory signaling pathways

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“NDA”	new drug application, an application submitted to the relevant regulatory authority for approval to market a new drug
“NF-κB p65”	nuclear factor kappa B p65, a subunit of the NF-κB transcription factor complex involved in inflammatory signaling
“NGP”	next-generation probiotic, a probiotic strain typically identified through modern microbiome research, that has relatively well-characterized mechanisms of action and is developed for specific therapeutic or health indications, distinct from conventional probiotic strains
“NRDL”	National Reimbursement Drug List, a list of pharmaceutical products that are fully or partially reimbursed by the national health insurance fund in China
“OM”	oral mucositis, inflammation and ulceration of the oral mucosa that may occur as a common complication of chemotherapy or radiotherapy in cancer patients
“OTC”	over-the-counter, referring to a drug that may be sold directly to consumers without a prescription
“PCC”	preclinical candidate, a candidate product selected after early-stage discovery, screening and optimization for further preclinical development
“PCT”	Patent Cooperation Treaty, an international treaty administered by the World Intellectual Property Organization (WIPO) that allows an applicant to seek patent protection for an invention simultaneously in multiple member countries by filing a single international patent application, which then enters the national or regional phase in each designated jurisdiction
“PD-1”	programmed cell death protein 1, an inhibitory immune checkpoint receptor primarily expressed on T cells that helps regulate T cell activity when engaged by its ligands
“PD-L1”	programmed death-ligand 1, an immune checkpoint protein expressed on certain normal cells and at higher-than-normal levels on some types of cancer cells, which can bind to PD-1 on T cells and dampen T cell activity
“pediatric rotavirus diarrhea”	refers to acute diarrhea in children caused by rotavirus, according to Frost & Sullivan, “pediatric rotavirus diarrhea” and “rotavirus infection” are highly overlapping clinical concepts in disease settings
“placebo”	a substance with no active therapeutic effect used as a control in clinical trials
“PPS”	per protocol set, an analysis population used for sensitivity or supportive efficacy analyses in a clinical trial, generally including subjects who complete the trial without major protocol deviations that may affect the efficacy evaluation, as specified in the statistical analysis plan

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“Pre-IND”	pre-investigational new drug, a regulatory communication with the relevant authority before submission or resubmission of an IND application
“primary endpoint”	the main pre-defined outcome measure used to evaluate a clinical trial’s primary objective
“probiotic raw materials”	microbial strains or related ingredient forms supplied as upstream ingredients for further formulation or processing into finished products
“PSA”	polysaccharide A, a zwitterionic capsular polysaccharide produced by <i>Bacteroides fragilis</i> that has been shown to modulate host immune responses
“psoriasis”	a chronic, immune-mediated inflammatory skin disease characterized by erythematous, scaly plaques, most commonly affecting the knees, elbows, trunk and scalp
“QbD”	Quality by Design, a systematic approach to pharmaceutical development that begins with predefined objectives and emphasizes product and process understanding and process control
“R&D”	research and development, the systematic activities undertaken to discover new knowledge and develop new or improved products, processes or technologies
“Rome IV criteria”	diagnostic criteria used for functional gastrointestinal disorders, including IBS-D
“SAD”	single ascending dose, an early-phase clinical trial design where small, sequential cohorts receive single doses of a drug at ascending dose levels to assess safety and tolerability
“SAE”	serious adverse event, an adverse event that results in death, is life-threatening, requires hospitalization or prolongation of hospitalization, results in disability or incapacity, or otherwise meets applicable seriousness criteria
“SCFAs”	short-chain fatty acids, a group of microbial metabolites that may affect immune responses and tumor cell growth
“second-generation LBP”	an LBP developed under a modern pharmaceutical development framework with defined indications, clinical evidence requirements and CMC controls
“SERT”	serotonin transporter, a membrane transport protein that reuptakes 5-HT from the synaptic or extracellular space, helping regulate serotonergic signaling, including in the gut-brain axis
“SGS”	a third-party testing, inspection and certification organization
“SMO”	site management organization, a third-party service provider that provides site-level operational support for clinical trials

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“SOP”	standard operating procedure, a documented set of step-by-step instructions for routinely performing a specific operation or process
“SS”	safety set, an analysis population used for safety analyses in a clinical trial, generally including all subjects who receive at least one dose of the investigational product, as specified in the statistical analysis plan
“STAT3”	signal transducer and activator of transcription 3, a signaling protein involved in pathways that may promote intestinal mucosal regeneration and healing
“TEAE”	treatment-emergent adverse event, an adverse event that emerges or worsens after initiation of study treatment
“TGI”	tumor growth inhibition, a measure used in preclinical oncology studies to assess the extent to which a treatment inhibits tumor growth
“Th1”	T helper 1 cell, a T cell subset involved in cell-mediated immune responses
“tight junction”	a structure between neighboring epithelial cells that helps maintain barrier integrity
“TLR2”	toll-like receptor 2, a pattern-recognition receptor involved in innate immune recognition and inflammatory signaling
“TLR4”	toll-like receptor 4, a pattern-recognition receptor involved in innate immune recognition and inflammatory signaling
“TNF- α ”	tumor necrosis factor alpha, a pro-inflammatory cytokine involved in inflammatory responses
“Treg cells”	regulatory T cells, a subpopulation of T cells that help modulate immune responses and maintain immune tolerance
“TSLP”	thymic stromal lymphopoietin, an upstream epithelial-derived cytokine involved in initiating and amplifying inflammatory responses in AD
“tumor microenvironment”	the cells, molecules and surrounding structures within and around a tumor that may influence tumor growth and treatment response
“UC”	ulcerative colitis, one of the two main types of inflammatory bowel disease, a long-term condition characterized by inflammation and ulcers of the colon and rectum
“visceral hypersensitivity”	increased sensitivity of internal organs, such as the intestine, to stimulation or distension
“ZO-1”	zonula occludens-1, a tight junction protein involved in maintaining intestinal epithelial barrier integrity