
GLOSSARY OF TECHNICAL TERMS

This glossary contains definitions of certain terms used in this document in connection with us and our business. Some of these may not correspond to standard industry definitions.

“ACC score”	anterior chamber cell score, a grading of inflammatory cells present in the anterior chamber of the eye, typically assessed by slit-lamp examination using a standardized scoring scale to quantify intraocular inflammation
“ACF score”	anterior chamber flare score, a clinical grading scale to quantify the severity of anterior chamber flare, the presence of protein and inflammatory material in the fluid in the front part of the eye. The flare is typically assigned a numerical grade from 0 to 4, with higher scores indicating more severe intraocular inflammation
“ADA”	anti-drug antibodies, antibodies produced by the immune system in response to a therapeutic drug, which may affect the drug’s efficacy, safety or pharmacokinetics
“AE”	adverse event, any untoward medical occurrence in a patient or clinical trial subject associated with the use of a drug or other therapy
“AMD”	age-related macular degeneration, a degenerative disease of the macula and a leading cause of vision loss in older adults
“anterior segment”	structures in the front part of the eye, including the cornea, anterior chamber, iris, ciliary body and lens. Many topical ophthalmic therapies primarily target the anterior segment
“AUC”	area under the concentration-time curve, a pharmacokinetic parameter that represents the total systemic exposure of the body to a drug over time, calculated as the area under the plasma drug concentration versus time curve
“BFS”	blow-fill-seal, a manufacturing technology that forms, fills and seals plastic containers in a single, automated and enclosed process, enabling the production of sterile, single-use liquid pharmaceutical products with reduced risk of contamination and high consistency of dosing
“bioavailability”	the fraction of an administered dose of drug that reaches the systemic circulation, which is one of the principal pharmacokinetic properties of drugs
“biologics”	medicinal products that are derived from living organisms or produced using biological processes, and typically comprise complex biological molecules or materials, such as proteins, antibodies and other biological substances

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“BQL”	below the qualification limit, concentration measurements which are too small for specific values to be assigned
“BTD”	breakthrough therapy designation, a regulatory status awarded to drugs by the NMPA that show substantial improvement over existing therapies for serious or life-threatening conditions, based on preliminary clinical evidence
“cataract”	a dense, cloudy area that forms in the lens of the eye which leads to vision loss
“CDMO”	contract development and manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing
“CFS score”	corneal fluorescein staining score, a clinical measure of damage to the surface of the cornea obtained by instilling fluorescein dye in the eye and grading the resulting staining pattern. The cornea is typically divided into five predefined zones (central, inferior, superior, temporal and nasal), each assigned a numerical score (abbreviated as cCFS, iCFS, sCFS, tempCFS and nCFS, respectively) according to a standard grading scale. A total corneal fluorescein staining score (abbreviated as “total CFS” or “tCFS”) is then calculated as the sum of the scores for the individual zones, with higher scores indicating more pronounced corneal surface damage
“C _{max} ”	the highest measured concentration of a drug in blood or plasma after administration
“cornea”	the transparent part of the coat of the eyeball that covers the iris and pupil and admits light to the interior
“corticosteroids”	class of steroid hormones that lowers inflammation in the body and reduces immune system activity
“CRO”	contract research organization, a company that provides support to pharmaceutical companies by providing a range of professional research services on a contract basis
“CRS”	chronic rhinosinusitis, a long-term inflammation of the nose and paranasal sinuses associated with symptoms such as nasal blockage, discharge, facial pressure and reduced sense of smell. Chronic rhinosinusitis is commonly classified into two forms: chronic rhinosinusitis with nasal polyps (CRSwNP) and chronic rhinosinusitis without nasal polyps (CRSSNP)

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“cyclosporine A” or “CsA”	an immunomodulatory agent used in ophthalmology primarily for the treatment of dry eye disease and other inflammatory ocular surface disorders
“cytokines”	small secreted proteins released by cells that have a specific effect on the interactions and communications between cells
“DED”	dry eye disease, a common condition in which the eyes do not produce enough tears or the tears evaporate too quickly, leading to ocular surface damage and symptoms such as dryness, irritation and visual disturbance
“DME”	diabetic macular edema, swelling in the central part of the retina (macula) due to leakage from damaged blood vessels in people with diabetes
“double-masked”	a type of clinical trial in which neither the participants nor the researchers know which treatment a specific participant is receiving, which helps prevent bias or expectations from influencing the results of the study
“epithelial defect”	a loss or break in the surface layer of epithelial cells, typically referring to a discontinuity in the corneal or conjunctival epithelium of the eye, exposing the underlying tissue
“fundus”	the inside back part of the eye, including the retina, optic nerve and blood vessels
“glaucoma”	a group of eye diseases characterized by progressive damage to the optic nerve, often associated with elevated intraocular pressure, which can lead to gradual loss of vision and, if left untreated, blindness
“Grade IIIA hospitals”	the largest and best regional hospitals in China designated as Grade III hospitals by the National Health Commission hospital classification system, typically having more than 500 beds, as for a comprehensive hospital providing high-quality professional healthcare services covering a wide geographic area and undertaking higher academic and scientific research initiatives. The Grade III hospitals are graded into three sub-levels (A, B and C) based on the assessment of competent authorities and Grade IIIA hospitals are the highest ranking hospitals among Grade III hospitals
“IC ₅₀ ”	the concentration of a drug or substance that produces 50% of its maximum inhibitory effect in a biological system
“IDMC”	independent data monitoring committee, an independent expert group that reviews data during a clinical trial to monitor safety and efficacy

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“immunogenicity”	the ability of a drug, particularly a biological product, to provoke an immune response in the body, including the formation of anti-drug antibodies
“IND”	investigational new drug, the application for which is the first step in the drug review process by regulatory authorities to decide whether to permit clinical trials
“inflammatory cytokine pathways”	cell signaling pathways activated by cytokines that trigger or regulate inflammation. Dysregulation of these pathways can contribute to many immune-mediated and inflammatory diseases
“innovative drug”	a drug that contains an active ingredient or combination of active ingredients that has not been authorized before, or a drug that contains an existing active ingredient or combination of active ingredients with improvements on its structure, formulation, route of administration or indication. Under relevant PRC chemical drug registration regulations, innovative drugs include class 1 drugs (innovative new drugs), class 2 drugs (improved new drugs) and class 5.1 drugs (innovative or improved new drugs that have been marketed abroad and apply for approval in China). Under relevant drug registration regulations in the United States, innovative drugs refer to new molecular entity drugs which are active ingredients that contain no active moiety that has been previously approved by the FDA in new drug applications or has been previously marketed as a drug in the United States
“interferon” or “IFN”	a family of signaling cytokines produced by host cells in response to viruses, other pathogens and immune stimuli, and act as key mediators of antiviral defense and immune regulation
“interleukin” or “IL”	a family of signaling cytokines produced by white blood cells and function as key mediators of immune cell communication, regulating cell proliferation, differentiation, motility and survival across both innate and adaptive immunity
“intraocular space”	the space within the eye that is filled by the vitreous humor (the clear gel-like substance between the lens and the retina)
“investigator-initiated trial” or “IIT”	a clinical study that is designed and initiated by an independent investigator who acts as the sponsor, instead of being initiated by a pharmaceutical company
“ <i>in vitro</i> ”	experiments or tests performed outside a living organism
“ <i>in vivo</i> ”	experiments or tests performed within a living organism

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“JAK”	Janus kinase, a family of tyrosine kinase enzymes (including JAK1, JAK2, JAK3 and TYK2) that transmit signals from various cytokine receptors involved in immune and inflammatory responses
“KOL”	key opinion leader, professional (in the context of the medical industries) who influence their peers’ medical practice
“LFA-1”	lymphocyte function-associated antigen-1, a protein found on the surface of certain white blood cells, including T cells. LFA-1 is an integrin adhesion molecule that helps immune cells adhere to other cells and migrate into tissues, and it plays an important role in immune responses and inflammation
“macula”	an oval-shaped pigmented area near the center of the retina which is responsible for central, high-resolution, color vision
“MOA”	mechanism of action, the specific way in which a drug produces its therapeutic effect in the body
“NDA”	new drug application, an application through which the drug sponsor formally proposes that the relevant regulatory authority approve a new drug for sales and marketing
“NIAU”	non-infectious anterior uveitis, an inflammation of the front part of the uvea that is not caused by infection and is often related to immune-mediated conditions
“NK”	neurotrophic keratitis, a rare degenerative disease of the cornea caused by impaired corneal nerve function, leading to reduced corneal sensitivity, poor healing and risk of corneal damage, ulceration and vision loss
“NSAIDs”	non-steroidal anti-inflammatory drugs, a class of drugs that reduce inflammation without using steroids
“oGvHD”	ocular graft-versus-host disease, an ocular manifestation of graft-versus-host disease that occurs after allogeneic hematopoietic stem cell or bone marrow transplantation, in which donor immune cells attack the recipient’s ocular tissues. This can cause severe dry eye, ocular surface inflammation, discomfort and visual disturbance, and can significantly affect quality of life
“ophthalmology”	a branch of medical science dealing with the structure, functions and diseases of the eye

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“pediatric uveitis”	inflammation of the uveal tract of the eye occurring in children. It can be associated with systemic autoimmune diseases and may lead to complications such as glaucoma or cataract if not adequately treated
“Phase I 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 II clinical trial”	a 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 drug for specific targeted diseases, and to determine dosage tolerance and optimal dosage
“Phase III clinical trial”	a study in which a drug is administered to an expanded patient population at geographically dispersed clinical trial sites to generate statistically sufficient data to evaluate the efficacy and safety of the drug for regulatory approval and to provide adequate information for the labeling of the product
“PK”	pharmacokinetics, the study of how the human body affects a drug over time, including its absorption, distribution, metabolism and excretion
“placebo”	a medical treatment or preparation with no specific pharmacological activity
“preclinical study”	research that tests a drug candidate on non-human subjects to gather efficacy and safety information to decide whether the drug candidate is ready for clinical trials in human participants
“preferred term”	the standardized medical term that represents a single medical concept and is used as the primary term for coding and analyzing safety data
“presbyopia”	an age-related loss of the eye’s ability to focus on near objects, usually becoming noticeable from around the age of 40, due to gradual stiffening of the lens
“primary endpoint”	the main outcome in a clinical trial that is used to assess whether a treatment is effective. The study is usually designed and statistically powered around this pre-specified endpoint
“randomized clinical trial”	a study in which the participants are divided by chance into separate groups that compare different treatments or other interventions

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“rescue medication”	medicine intended to relieve symptoms immediately
“retina”	a thin layer of tissue that lines the back of the eye on the inside
“rNGF”	recombinant nerve growth factor, a laboratory-produced form of nerve growth factor used therapeutically to support the survival, maintenance and regeneration of certain nerve cells
“RVO”	retinal vein occlusion, blockage of a retinal vein, leading to retinal swelling, hemorrhage and potential vision loss
“SAE”	serious adverse event, AE that results in death, or is life-threatening, or requires in-patient hospitalization or causes prolongation of existing hospitalization, or results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect
“SANDE scores”	scores derived from the symptom assessment in dry eye questionnaire, a patient-reported instrument that uses visual analog scales to quantify the frequency and severity of dry eye symptoms
“Schirmer’s test”	a diagnostic test to measure tear production, in which a strip of filter paper is placed in the lower eyelid and the length of the wetted portion is measured over a fixed period
“scleritis”	a severe, often painful inflammation of the sclera, the white outer wall of the eye. It is frequently associated with systemic autoimmune diseases and may threaten vision if not properly managed
“secondary endpoint”	outcome measured in a clinical trial to further evaluate the effect of a treatment on other relevant aspects of disease or patient benefit, beyond the primary endpoint
“small molecule”	a low molecular weight compound that can enter cells easily and interact with specific targets such as proteins or enzymes
“SMO”	site management organization, a company that provides operational support in managing clinical trial sites
“SS-DED”	Sjögren’s syndrome dry eye disease, a chronic autoimmune disease in which the immune system attacks glands that produce tears and saliva, typically causing dry eyes and dry mouth and sometimes affecting other organs

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“STAT”	signal transducer and activator of transcription, a family of protein that transmit signals from cytokines and cell-surface receptors to the cell nucleus, where they regulate the expression of specific genes
“systemic exposure”	the extent and duration to which a drug reaches the systemic circulation and tissues of the body after administration, usually described by pharmacokinetic parameters such as concentration over time
“T cell”	a type of white blood cell that develops in the thymus and plays a central role in adaptive immunity. Major subsets include CD4 ⁺ helper T cells, which support other immune cells, and CD8 ⁺ cytotoxic T cells, which destroy target cells presenting foreign or abnormal antigens
“TEAE”	treatment-emergent adverse event, an adverse event that arises or worsens after the start of study treatment in a clinical trial, regardless of whether it is considered related to the treatment
“tear film”	a thin fluid layer that covers the outer surfaces of the eye
“T-helper cell” or “Th cell”	a type of T cell that activates other immune cells by releasing cytokines and play an important role in the adaptive immune system, which is also known as CD4 ⁺ T cells
“toxicity”	the degree to which a substance or a mixture of substances can harm humans or animals. Acute toxicity involves harmful effects in an organism through a single or short-term exposure
“transmucosal delivery”	a method of drug delivery in which a medicine is absorbed through a mucous membrane (for example, oral, nasal or ocular surfaces) into the body, rather than through the skin or by injection
“uvea”	the middle, vascular layer of the eye, lying between the sclera (white of the eye) and the retina. The uvea consists of the iris, ciliary body and choroid
“uveitis”	inflammation of the uveal tract of the eye. Uveitis can be classified by anatomical location as anterior uveitis, intermediate uveitis, posterior uveitis or panuveitis, and by cause as infectious uveitis or non-infectious uveitis
“VAS”	visual analog scale, a patient-reported outcome measure in which a person rates the severity of symptoms or discomfort along a continuous line between two end-points

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“VEGF”	vascular endothelial growth factor, a signaling protein that stimulates the growth of new blood vessels
“vehicle”	in pharmaceutical formulations, the inert substance (such as a liquid, gel or cream base) used to carry the active ingredient and facilitate its administration
“VKC”	vernal keratoconjunctivitis, a chronic, recurrent allergic disease of the eye that typically affects children and young adults. It involves inflammation of the conjunctiva and cornea, and can cause intense itching, photophobia and, in severe cases, corneal damage