
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.

“abbreviated NDA”	abbreviated new drug application, an application for a generic drug to an approved drug
“acetazolamide”	a drug that inhibits the activity of carbonic anhydrase, a type of enzyme that helps regulate pH and fluid balance. Acetazolamide is used in the treatment of glaucoma and in the prevention of acute mountain sickness
“AE”	adverse event, any untoward medical occurrence in a patient or clinical trial subject associated with the use of a drug or other therapy
“agonist”	a drug or other substance that activates a receptor to produce a specific physiological effect
“allergen”	a substance that causes an allergic reaction
“AMD”	age-related macular degeneration, a disease that causes damage to the macula and leads to progressive loss of central vision
“anterior chamber”	the front part of the eye between the cornea and the iris
“anticholinergic”	a group of substances that block the action of acetylcholine, a kind of neurotransmitter, in the nervous system
“antihistamine”	a synthetic drug that suppresses the activity of histamine, a substance present in tissues as a mediator of allergic reactions. Antihistamine is often used to treat allergic rhinitis and other allergies
“anti-VEGF drug”	a drug that suppresses the activity of VEGF
“aqueous humor”	a transparent watery fluid that fills both the anterior and posterior chambers of the eye
“arachidonic acid”	unsaturated fatty acid that occurs in most animal fats and is considered essential in animal nutrition

GLOSSARY OF TECHNICAL TERMS

“asthma”	a chronic lung disorder that is marked by recurring episodes of reversible airway obstruction manifested by labored breathing accompanied especially by wheezing and coughing and by a sense of constriction in the chest
“atropine”	atropine or atropine sulfate, a medication used to treat certain types of nerve agent poisonings and certain types of slow heart rates
“beta-blocker”	any of a class of drugs that decrease the rate and force of heart contractions and lower high blood pressure by blocking the activity of beta-receptors in the nervous system
“bimatoprost”	a type of PGA used to treat increased intraocular pressure, sold under the trade name Lumigan
“biosimilar”	a drug which is designed to have the same amino acid sequence and the equivalent (but not identical or clinically better) active properties as compared to, and which is not necessarily clinically interchangeable with, the reference drug
“biosynthesis”	the production of a complex chemical compound from simpler precursors in a living organism
“blepharitis”	a disease characterized by the inflammation of the margin of the eyelids
“bridging trial”	a supplemental trial performed in a new region to provide clinical data on efficacy, safety and dosage, which allows for the extrapolation of foreign clinical data to the population in the new region
“brimonidine”	a drug indicated for lowering intraocular pressure in open-angle glaucoma
“CAC”	conjunctival allergen challenge, a conjunctival provocation test that evaluates the efficacy of anti-allergic agents by instilling allergens on the ocular surface
“capillary”	any of the minute blood vessels that form networks throughout the bodily tissues

GLOSSARY OF TECHNICAL TERMS

“carbonic anhydrase”	a class of enzymes that catalyze the interconversion between carbon dioxide and water and the dissociated ions of carbonic acid, thereby helping regulate pH and fluid balance
“cataract”	a dense, cloudy area that forms in the lens of the eye which leads to vision loss
“cetirizine”	cetirizine hydrochloride, a second-generation of antihistamine that binds competitively to histamine receptor sites to reduce swelling, itching, and vasodilation with better safety and efficacy
“chronic NIU-PS”	chronic non-infectious uveitis affecting the posterior segment of the eye
“CMC”	chemistry, manufacturing and controls, a process which mainly includes defining a drug product’s characteristics, formulation development and product testing to ensure that the product is safe, effective and consistent between batches
“CMO”	contract manufacturing organization, a company that manufactures drug products for pharmaceutical companies on a contract basis
“collagen”	a family of proteins that are the primary structural component of connective tissues, such as skin and cartilage
“confirmatory clinical phase III trial”	a phase III clinical trial which is generally used to provide additional or firm evidence of efficacy or safety, and an active control is required. Additionally, confirmatory clinical phase III trial also evaluates the efficacy of a drug candidate in comparison with currently available drugs. In China, a confirmatory clinical phase III trials is usually suggested by the CDE as part of a bridging study to compare the efficacy and safety of an in-licensed drug candidate against currently available drugs in China.
“conjunctival epithelium”	non-keratinized, stratified layer that together with the corneal epithelium provides stability to the tear film

GLOSSARY OF TECHNICAL TERMS

"conjunctival hyperemia"	conjunctival reaction that appears as dilation and redness of the conjunctival vessels
"conjunctivitis"	a disease characterized by the inflammation of the conjunctiva, the membrane which lines the inner surface of the eyelids and covers the surface of the eyeball
"cornea"	the transparent part of the coat of the eyeball that covers the iris and pupil and admits light to the interior
"corticosteroid"	a class of steroid hormones that are produced by the adrenal cortex, a part of the adrenal gland
"CRO"	contract research organization, a company that provides support to pharmaceutical companies by providing a range of professional research services on a contract basis
"cyclosporine"	a drug that suppresses the immune system and is used especially to prevent rejection of transplanted organs
"cytokines"	small secreted proteins released by cells that have a specific effect on the interactions and communications between cells
"D"	the degree of myopia
"degranulation"	immediate response of tissue mast cells to wounding, releasing preformed mediators into the local connective tissue which results in the recruitment of cellular and soluble effectors
"demodex"	a parasitic mite that infests the hair follicles and skin of humans and domestic animals
"dermatology"	a branch of science dealing with the skin, its structure, functions and diseases
"dexamethasone"	dexamethasone or dexamethasone sodium phosphate, a synthetic steroid hormone used especially as an anti-inflammatory agent
"DME"	diabetic macular edema, a complication of diabetes that causes damage to the macula

GLOSSARY OF TECHNICAL TERMS

“double-masked clinical trial”	a type of clinical trial in which neither the participants nor the research team know which treatment a specific participant is receiving, which helps prevent bias or expectations from influencing the results of the study
“dry eye”	a condition associated with inadequate tear production and marked by redness, itching and burning of the eye
“edema”	swelling that occurs when too much fluid becomes trapped in the tissues of the body
“emedastine”	a second-generation antihistamine used in eye drops to alleviate the symptoms of allergic conjunctivitis
“endophthalmitis”	an infection of the tissues or fluids inside the eyeball
“epithelia”	tissues that line the outer surfaces of organs and blood vessels throughout the body, as well as the inner surfaces of cavities in many internal organs
“FA”	fluocinolone acetonide, a corticosteroid primarily used to reduce inflammation and relieve itching
“fibrin”	a blood component involved in the clotting process which can be used as a matrix for tissue engineering applications
“fibroblast”	a type of biological cell that synthesizes the extracellular matrix and collagen, produces the structural framework (stroma) for animal tissues, and plays a critical role in wound healing
“fluoroquinolone”	any of a class of synthetic antibiotics which are fluorinated quinolones, and which have broad-spectrum antibacterial activity and work by interfering with bacterial DNA synthesis
“fluticasone propionate”	a corticosteroid with anti-inflammatory properties
“generic drug”	a drug that is chemically identical to an original drug and is generally available in the same strength and dosage forms as the original

GLOSSARY OF TECHNICAL TERMS

“glaucoma”	a group of eye diseases that are usually characterized by progressive structural and functional changes of the optic nerve, leading to a typical appearance of the optic disc and visual field damage if untreated
“glucocorticoid”	any of the steroid hormones produced in the adrenal cortex, a part of the adrenal gland, which are associated with carbohydrate metabolism
“GCP”	good clinical practice, a quality standard for conducting clinical trials
“GMP”	good manufacturing practice, a system for ensuring that products are consistently produced and controlled according to quality standards
“Grade II hospital”	a medium-sized city-, county- or district-level hospital in China with a bed capacity of 101 to 500
“Grade III hospital”	a large city-, provincial- or national-level hospital in China with a bed capacity exceeding 500
“gyrase”	any of a class of bacterial enzymes that catalyze the breaking and rejoining of bonds linking certain molecules in circular DNA
“H1”	histamine-1
“histamine”	a biologically active substance that is present in tissues as a mediator of allergic reactions
“hyaluronic acid”	sodium hyaluronate, a type of acid naturally produced by the human or animal body to keep tissues lubricated and moist
“hydrophilia”	a tendency to absorb fluid
“hyperosmolarity”	a condition where the solute concentration of the bodily fluid, which is the amount of solutes and particles that are dissolved in the bodily fluid, abnormally increases
“hypoxia”	a condition in which the body or a region of the body does not have adequate oxygen supply at the tissue level

GLOSSARY OF TECHNICAL TERMS

"IgE"	Immunoglobulin E
"IgG1"	immunoglobulin G1, a type of antibody in blood circulation that controls infections in the human body
"immuno-suppressant"	a class of drugs that suppress, or reduce, the strength of the body's immune system
"inciting agent"	a factor (as an infectious agent) that is the essential causative agent of a particular disease
"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. Also known as clinical trial application, or CTA, in China
"interleukin-4 cytokine"	a key cytokine in the development of allergic inflammation
"intravitreal implant"	a drug delivery system, injected or surgically implanted in the vitreous of the eye, for sustained release of drug to the posterior and intermediate segments of the eye
"IOP"	intraocular pressure
"iris"	a thin, annular structure in the eye, responsible for controlling the diameter and size of the pupil and thus the amount of light reaching the retina
"ITT population"	intent-to-treat population, a group of subjects in a clinical trial that are intended to represent suitable patients and to be reflective of the treatment outcome if the treatment is used in clinical practice
"keratoplasty"	a surgery for restoration of the cornea
"latanoprost"	a type of PGA used to treat increased intraocular pressure, sold under the trade name Xalatan
"leukocyte"	white blood cells
"leukotriene"	any of a group of arachidonic acids that participate in allergic responses

GLOSSARY OF TECHNICAL TERMS

“lipocortins”	also known as annexin, a group of proteins that suppress phospholipase A2
“macula”	an oval-shaped pigmented area near the center of the retina which is responsible for central, high-resolution, color vision
“macular edema”	a condition that occurs when blood vessels in the retina leak, which can cause permanent vision loss if untreated
“MAH”	marketing authorization holder, who is allowed to market a drug product within a certain region or country
“mast cells”	immune cells of the myeloid lineage which are present in connective tissues throughout the body
“mCNV”	myopic choroidal neovascularization, a complication of myopia, which causes the creation of new blood vessels in the choroid, a vascular membrane of the eyeball
“membrane phospholipid”	complex molecules that, like proteins, harbor functional groups known to coordinate copper ions
“muco-adhesion”	the adhesion between two materials, at least one of which is a mucosal surface
“moxifloxacin”	moxifloxacin or moxifloxacin hydrochloride, an antibiotic used to treat a number of bacterial infections
“MRCT”	multi-regional clinical trial, a clinical trial that is conducted in different regions under a common trial design for simultaneous global new drug development
“mucosa”	the membrane that covers the inside surface of organs
“myopia”	a refractive condition in which the image of distant objects is focused in front of, rather than on, the retina
“nanocrystal”	a nanoscale crystal
“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

GLOSSARY OF TECHNICAL TERMS

"neurotransmitter"	a substance that transmits nerve impulse
"NIPU"	non-infectious posterior uveitis
"NO"	nitric oxide
"ocular hypertension"	an eye pressure of greater than 21 mm Hg
"off-label use"	medication which is being used in a manner not specified in the approved packaging label
"ophthalmology"	a branch of medical science dealing with the structure, functions and diseases of the eye
"optic nerve"	the nerve layer that lines the back of the eye and senses light and creates impulses to be transmitted to the vision centers of the brain
"orbital fibrosis"	a class of rare genetic disorders affecting one or more of the muscles that move the eyeballs
"osteoarthritis"	a joint disease characterized by destruction of articular cartilage, usually occurring among the elderly and causing pain and stiffness
"OTC drugs"	over-the-counter drugs, drugs that are sold directly to a consumer without a prescription
"pancreatitis"	a disease characterized by inflammation of the pancreas
"pathogenesis"	the mechanism whereby a disease is produced
"pediatric"	the branch of medicine that involves the medical care of infants, children and adolescents
"PGA"	prostaglandin analog, a class of drugs that bind to prostaglandin receptors
"phakic eye"	an eye containing a phakic intraocular lens, which is placed on top of the natural lens and is typically intended to correct refractive errors and treat myopia

GLOSSARY OF TECHNICAL TERMS

“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
“phosphate”	a compound derived from a phosphoric acid, usually a constituent of cereals, minerals and rocks
“phospholipase A ₂ ”	an enzyme which releases fatty acids from glycerol
“photophobia”	aversion to or avoidance of light, especially as the result of discomfort caused by ocular disorders and certain neurological diseases
“photoreceptor”	a cell or group of cells capable of converting a visible light stimulus into an electrical signal in a nerve
“placebo”	a medical treatment or preparation with no specific pharmacological activity
“plasma cells”	a type of immune cells that make large amounts of a specific antibody
“preclinical research”	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 subjects

GLOSSARY OF TECHNICAL TERMS

“primary efficacy endpoint”	a clinical or laboratory outcome measured in an individual after randomization that allows one to test the primary hypothesis and provides the means of assessing whether a therapy is effective compared with its control
“prostaglandin”	any of a large group of fatty acids which have a wide variety of physiological effects, especially in the control of smooth muscle activity and in inflammatory responses
“pruritus”	the medical term for itch
“ptosis”	a drooping or falling of the upper eyelid
“pupil”	the opening in the iris through which light passes through to the lens
“pyrazole”	a compound whose molecule is an unsaturated five-membered ring containing adjacent nitrogen atoms
“quinolones”	any of a class of synthetic antibacterial drugs that inhibit the replication of bacterial DNA
“raceanisodamine”	a substance with the effect of muscle relaxation
“randomized clinical trial”	a study in which the participants are divided by chance into separate groups that compare different treatments or other interventions
“ranibizumab”	an antibody fragment that inhibits the growth of new blood vessels and is used for the treatment of wet AMD
“receptor antagonist”	a type of drug that blocks or dampens a biological response by binding to and blocking a receptor rather than activating it like an agonist
“renal neoplasm”	an abnormal mass of tissue in kidney that results when cells divide abnormally, forming a tumor
“retina”	a thin layer of tissue that lines the back of the eye on the inside
“rhinitis”	inflammation of the mucous membrane of the nose

GLOSSARY OF TECHNICAL TERMS

"RVO"	retinal vein occlusion, a disease due to the blockage of the retinal vein, the blood vessel that drains the retina, which can lead to blurry vision or loss of vision
"SAEs"	serious adverse events, AEs that result in death, or is life-threatening, or require in-patient hospitalization or cause prolongation of existing hospitalization, or result in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect
"sclera"	the dense fibrous opaque white outer coat enclosing the eyeball except the part covered by the cornea
"sham injection"	the injection of a placebo or agent that simulates a drug being administered in a clinical trial
"standard of care"	a treatment that is accepted and widely used by medical experts as a proper and standard treatment for a certain disease
"steroid"	a large class of natural or synthetic organic compounds characterized by a nucleus of 17 carbon atoms in the form of four fused rings, which includes many types of hormones and glycosides, and many of which have important pharmacological uses
"tachycardia"	a common type of heart rhythm disorder in which the heart beats faster than normal while at rest
"TEAE"	treatment-emergent adverse event, an undesirable event not present prior to medical treatment, or an already present event that worsens either in intensity or frequency following the treatment
"tear film"	a thin fluid layer that covers the outer surfaces of the eye
"teratogenic risk"	risk that a certain substance could result in a baby being born with a birth defect
"Th2 cell"	T helper type 2 cell, a type of T cell that plays an important role in the immune system
"tonometry"	a procedure performed to determine the IOP

GLOSSARY OF TECHNICAL TERMS

"topoisomerase"	any of a class of enzymes that reduce winding in DNA by breaking and rejoining one or both strands of the DNA molecule
"trabecular"	a small, often microscopic, tissue element in the form of a small beam, strut or rod that supports or anchors a framework of parts within a body or organ
"type 2 diabetes mellitus"	formerly known as adult-onset diabetes, a type of diabetes characterized by high blood sugar, insulin resistance and relative lack of insulin
"tyrosine kinase"	an enzyme that can transfer a phosphate group to a protein in a cell
"uveoscleral outflow"	drainage of ocular aqueous humor from the anterior chamber into the anterior chamber angle other than through the trabecular meshwork
"vasodilation"	the widening of blood vessels
"VEGF"	vascular endothelial growth factor, a signal protein produced by cells that stimulates the formation of blood vessels
"vehicle"	a vehicle control is used in studies in which a substance (<i>e.g.</i> , saline or mineral oil) is used as a vehicle for a solution of the experimental compound, and the supposedly innocuous substance is used alone without the experimental compound in order to determine whether the vehicle alone causes any effects
"visual cortex"	a part of the brain that processes visual information
"vitreous humor"	clear gel that fills the space between the lens and the retina of the eyeball
" γ -aminobutyric acid"	gamma aminobutyric acid, the major inhibitory neurotransmitter that reduces neuronal excitability throughout the nervous system