

GLOSSARY OF TECHNICAL TERMS

This glossary 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.

“AED”	anti-epileptic drug, a drug intended to prevent or control epileptic seizures and used in the treatment of epilepsy, whether as monotherapy or adjunctive therapy
“agitation”	a state of excessive motor activity, emotional distress, and irritability, often associated with disruptive or aggressive behavior
“allergen”	a substance capable of inducing a hypersensitivity reaction in susceptible individuals
“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
“ASM”	anti-seizure medication, pharmaceutical agents designed to suppress or prevent abnormal electrical discharges in the brain that trigger epileptic seizures
“AUC”	area under the concentration-time curve, a pharmacokinetic parameter used to measure the extent of systemic drug exposure over time
“BLA”	biologics license application
“CAGR”	compound annual growth rate
“cancer pain”	pain caused by cancer itself or by cancer treatment
“CGRP”	calcitonin gene-related peptide, a neuropeptide involved in migraine pathophysiology and pain signaling
“CIBP”	cancer-induced bone pain
“CIndU”	chronic inducible urticaria, a subtype of chronic urticaria in which wheals, angioedema, or both recur for more than six weeks and are triggered by specific and reproducible stimuli
“CMO”	contract manufacturing organization, a company that provides drug manufacturing services on a contract basis
“CNS”	central nervous system, a system that comprises the brain and spinal cord, responsible for processing sensory information and coordinating bodily functions. It serves as the primary target for therapies addressing neurological and psychiatric disorders

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“cognitive impairment”	impairment in mental processes such as attention, memory, learning and executive function
“COMT inhibitors”	catechol-O-methyltransferase inhibitors, a class of drugs that inhibit the catechol-O-methyltransferase enzyme and are used to reduce levodopa metabolism and prolong levodopa’s effect in the treatment of Parkinson’s disease
“COX-2 inhibitors”	selective cyclooxygenase-2 inhibitors, a subclass of non-steroidal anti-inflammatory drugs that reduce pain and inflammation by selectively inhibiting the cyclooxygenase-2 enzyme
“CRO”	contract research organization, a company that provides a range of professional research services on a contract basis
“CSO”	contract sales organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of services for the development and commercialization of new drugs, medical devices, and other healthcare products
“CSU”	chronic spontaneous urticaria, a condition characterized by the recurrent appearance of itchy hives or welts lasting for six weeks or longer, often without an identifiable cause
“CU”	chronic urticaria
“cytokines”	small signaling proteins released by cells that regulate immunity, inflammation and hematopoiesis
“dopamine agonists”	a compound that activates dopamine receptors in the absence of dopamine
“dose titration”	the process of adjusting the dose of a drug to achieve the desired therapeutic effect while minimizing adverse effects
“epilepsy”	a group of non-communicable neurological disorders characterized by recurrent epileptic seizures
“extrapyramidal symptoms”	drug-induced movement disorders that may include dystonia, parkinsonism, akathisia and tardive dyskinesia
“first-line”	with respect to any disease, the first line treatment refers to the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment. It is also called primary treatment or therapy
“GABA”	gamma-aminobutyric acid, the principal inhibitory neurotransmitter in the central nervous system
“GCP”	good clinical practice, an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans

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“gepants”	a class of drugs that act as calcitonin gene-related peptide receptor antagonists and are used in the acute treatment and, for certain agents, the preventive treatment of migraine
“GHG”	greenhouse gas
“GFA”	gross floor area
“HS&E”	health, safety and environment
“hypersensitivity”	an objectively reproducible set of symptoms or signs initiated by exposure to a defined stimulus at a dose tolerated by normal individuals
“IgE”	immunoglobulin E, a class of antibodies involved in allergic reactions and defense against certain parasites
“infiltration injection”	a method of drug administration in which an anesthetic or analgesic agent is injected directly into tissues at or near the site requiring pain control
“IRB”	Institutional Review Board
“MAO-B inhibitors”	monoamine oxidase B inhibitors, a class of drugs that inhibit the enzyme monoamine oxidase type B. In EMA product materials, MAO-B inhibitors are described as blocking monoamine oxidase type B, which breaks down dopamine in the brain
“migraine”	a primary headache disorder characterized by recurrent headache attacks, with or without aura, and associated symptoms
“monoclonal antibodies”	antibodies capable of binding to specific antigens and inducing immunological responses against the target antigens. Monoclonal antibodies when used as a cancer treatment have the ability to bind only to cancer cell-specific antigens and interrupt the growth of cancer cells to achieve efficient treatment with low dosages and less toxic side effects than traditional chemotherapy
“monotherapy”	therapy that uses a single drug to treat a disease or condition
“NDA”	new drug application
“neuropathic pain”	pain caused by a lesion or disease affecting the somatosensory nervous system
“non-opioid analgesics”	analgesic drugs that relieve pain without acting as opioids or binding to opioid receptors, and that are used to manage pain through other pharmacological mechanisms
“NSAID”	non-steroidal anti-inflammatory drug, a class of medicines commonly used to relieve pain and inflammation

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“NRDL”	National Reimbursement Drug List for Basic Medical Insurance, Work Injury Insurance and Maternity Insurance (《國家基本醫療保險,工傷保險和生育保險藥品目錄》)
“opioids”	a class of drugs that act on opioid receptors to produce analgesia and are commonly used for the management of moderate to severe pain
“OSF”	oral soluble film, a thin oral dosage form designed to dissolve in the mouth and release the active ingredient without the need for swallowing a conventional tablet
“osteoarthritis pain”	pain associated with osteoarthritis, a degenerative joint disease characterized by the progressive destruction of articular cartilage and other joint tissues
“OTC”	over-the-counter, referring to drugs that may be supplied without a prescription
“PD”	Parkinson’s disease, a brain disease that causes problems with movement, as well as mental health, sleep, pain and other health issues, and whose symptoms worsen over time
“phase 1 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 2 clinical trial”	a study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, preliminarily evaluate the efficacy of the product for specific targeted diseases, and determine dosage tolerance and optimal dosage
“phase 3 clinical trial”	a 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 product’s labeling
“postoperative pain”	acute pain occurring after a surgical procedure
“schizophrenia”	a mental illness characterized by significant impairments in perception and changes in behavior, which may include persistent delusions, hallucinations, disorganized thinking, highly disorganized behavior, and impaired functioning
“sustained-release granule formulation”	a granule dosage formulation designed to release the active pharmaceutical ingredient gradually over an extended period of time so as to maintain therapeutic drug levels for a longer duration after administration

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“SR”	sustained-release
“SV2A”	synaptic vesicle protein 2A, a synaptic vesicle membrane protein involved in the regulation of neurotransmitter release
“urticaria”	a vascular reaction of the skin characterized by the transient appearance of wheals and associated pruritus
“VBP”	volume-based procurement
“voltage-gated sodium channels”	transmembrane ion channels that open in response to changes in membrane potential and are involved in the initiation and propagation of action potentials