
GLOSSARY OF TECHNICAL TERMS

In this document, unless the context otherwise requires, explanations and definitions of certain terms used in this document in connection with our Group and our business shall have the meanings set out below. The terms and their meanings may not correspond to standard industry meaning or usage of these terms.

“adenovirus”	a DNA virus originally identified in human adenoid cell culture, causing infections of the respiratory system, conjunctiva and gastrointestinal tract;
“adjuvant”	a substance that may be added to a vaccine to enhance the immune response to an antigen;
“adverse event” or “AE”	any untoward medical occurrence in a patient or clinical investigation subject administered a drug or other pharmaceutical product during clinical trials, which does not necessarily have a causal relationship with the use of drug;
“antibody” or “immunoglobulin”	a protective Y-shaped protein produced by B cells that the immune system uses to recognize and respond to invading foreign substance (antigens) such as bacteria and viruses;
“antigen”	the substance that is capable of activating the immune system to initiate an immune response, specifically activating lymphocytes, which are the infection-fighting white blood cells;
“attenuated vaccine” or “live attenuated vaccine”	a vaccine created by reducing the virulence of a pathogen, but still keeping it viable (or “live”);
“B cell”	a type of white blood cell that can produce specific antibodies after being stimulated by an antigen;
“bioreactor”	a device that provides a suitable environment for the biological reaction process utilizing culture media, certain gases (such as air, oxygen, nitrogen, and carbon dioxide) and other necessary substances;
“BLA”	biologics license application;
“carrier protein”	protein-based molecules to conjugate with capsule polysaccharide to enhance immunogenicity;

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“CCID50”	cell culture infectious dose 50, the amount of virus required to infect 50% of cultured cells in a sample. It is a measure used to quantify the concentration of infectious virus in a sample;
“CD4 ⁺ T cells”	a type of important T lymphocyte that helps coordinating the immune response by stimulating and regulating other immune cells to fight infections. CD4 ⁺ T cells plays an important role in coordinating the body’s immune response;
“CHO cell”	Chinese hamsters ovary cell, which is widely used in the biopharmaceutical industry to produce recombinant proteins;
“CMC”	chemistry, manufacturing and controls, processes used in preclinical and clinical development stages to ensure that pharmaceutical and biopharmaceutical drug products are consistently effective, safe and high quality for consumers;
“Class I vaccine”	a vaccine that the Chinese government provides to its citizens free of charge and that citizens should be vaccinated in accordance with relevant government regulations, including vaccines determined in the national immunization program, additional vaccines required by provincial government in the implementation of national immunization programs and vaccines used in emergency vaccination or mass vaccination organized by the government at county-level or above, or their respective healthcare department;
“Class II vaccine”	a vaccine that is voluntarily vaccinated by citizens in China, and the cost of which is paid by the recipient;
“clinical trial”	a research study for finding or validating the therapeutic and protective effects and side effects of test drugs to determine the safety and efficacy of such drugs;
“column chromatography”	a chromatography method used to separate a single chemical compound from a mixture;
“combination vaccines”	vaccines that can prevent two or more infectious diseases;

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“conjugate”	chemically link bacterial capsular polysaccharide to a protein to enhance immunogenicity;
“CRO”	contract research organization, a company that provides support to pharmaceutical companies by providing a range of professional research services on a contract basis;
“dendritic cells (DC)”	cells that constantly monitor their surroundings for potential pathogens such as viruses and bacteria, detect dangers and initiate and regulate adaptive immune responses;
“emulsion”	a mixture of two or more liquids that are normally immiscible (unmixable or unblendable) owing to liquid-liquid phase separation;
“epitopes”	part of an antigen that is recognized by adaptive immune responses, specifically by T cell and B cell receptors and antibodies;
“fetal bovine serum”	serum components isolated from the blood of fetal bovine;
“GLP”	Good Laboratory Practice, a quality management system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported;
“GMP”	Good Manufacturing Practice, guidelines and regulations from time to time issued pursuant to the PRC Drug Administration Law (《中華人民共和國藥品管理法》) as part of quality assurance which aims to minimize the risks of contamination, cross contamination, confusion and errors during the manufacturing process of pharmaceutical products and to ensure that pharmaceutical products subject to these guidelines and regulations are consistently produced and controlled in conformity to quality and standards appropriate for their intended use;

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“GMT”	geometric mean titers, the geometric mean of antibody titer for a group of subjects calculated by multiplying all observed antibody titer values and taking the n^{th} root of this number, where n is the number of subjects with available data;
“herpes zoster”	also known as shingles, a viral infection that causes a painful rash;
“IgG”	Immunoglobulin G, the most common type of antibody which is found in blood and other body fluids, and protects against bacterial toxin and viral infections;
“immune response”	the process by which the body’s immune system is stimulated by antigens;
“immunogenicity”	the ability of a particular substance, such as an antigen, to provoke an immune response in the body of a human and other animal;
“inactivated vaccine”	a vaccine prepared by inactivating cultured viral particles, bacteria, or other pathogens through radiation, heat or chemical reagent;
“ <i>in vivo</i> ”	Latin for “within the living”, studies <i>in vivo</i> are those in which the effects of various biological or chemical substances are tested on whole, living organisms including animals, humans and plants, as opposed to a partial organ or tissue or deceased organism, or those done <i>in vitro</i> ;
“IND”	investigational new drug or investigational new drug application;
“influenza” or “flu”	highly infectious respiratory diseases caused by influenza viruses, characterised by sudden onset of high fever, aching muscles, headache, fatigue and a hacking cough. Serious outcome of influenza can result in hospitalization or death;
“KOL” or “key opinion leader”	influencers and trusted persons who have expert product knowledge and influence in a respective field and are an important part of burgeoning industries and businesses in China, including biotech/pharmaceutical industries;

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“lot release”	the supervisory and administrative system by which the NMPA designates a drug inspection institution to conduct document review, on-site verification and sample inspection in connection with vaccine products, blood products, <i>in vitro</i> diagnostics for blood screening, or any other biological products as described by the NMPA, before any batch of such products can be marketed or exported. Any batch of products failing in the lot release inspection or approval shall not be marketed or imported;
“mRNA”	messenger ribonucleic acid, a single-stranded molecule of RNA that contains a coding sequence of a gene, and is translated by a ribosome in the process of synthesizing a protein;
“NDA”	new drug application;
“neutralizing antibodies”	a type of antibodies that can bind to and neutralize the activities of pathogens such as viruses or toxins;
“pathogen”	a bacteria, virus or other microorganism that can cause disease;
“PCV24”	24-valent pneumococcal conjugate vaccine;
“Phase I clinical trial”	study in which a drug is tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, an early indication of its effectiveness;
“Phase II clinical trial”	study in which a drug is administered to a limited 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 III clinical trial”	study in which a drug is administered to an expanded 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 and to provide adequate information for the labeling of the product;

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“pneumococcal disease”	an infection that is caused by the <i>Streptococcus pneumonia</i> bacterium and can result in pneumonia, infection of the blood, middle-ear infection, or bacterial meningitis;
“pneumonia”	inflammation of the lungs, usually caused by an infection;
“polysaccharide”	a biological macromolecule made up of several simple sugars that are sequentially connected;
“PPSV23”	23-valent pneumococcal polysaccharide vaccine;
“rabies”	a disease that is caused by the rabies virus transmitted through animal bites to humans and is almost always fatal following the onset of clinical symptoms;
“recombinant”	DNA, proteins, cells, or organisms that are made by combining genetic material from two different sources;
“recombinant protein vaccine”	one category of vaccines, which comprise protein antigens produced in a heterologous expression system (<i>e.g.</i> , cells or yeast);
“RSV”	respiratory syncytial virus, a common respiratory virus that affects the nose, throat and lungs;
“SAE”	serious adverse events, any untoward medical occurrence in human drug trials that at any dose: results in death; is life threatening; requires inpatient hospitalization or causes prolongation of existing hospitalization; results in persistent or significant disability/incapacity; may have caused a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage;
“seroconversion”	the production of antibodies in the blood of a person who did not have the antibodies before. Testing for seroconversion can be used to see how well the body’s immune system responds to a vaccine;
“serotype”	a group of organisms, microorganisms or cells distinguished by their shared specific surface antigens;

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“split-virion vaccine”	a type of vaccine that is produced by using a chemical agent or physical method to disrupt the viral envelope and split open the viral particles;
“T cell”	cells that originate in the thymus, mature in the periphery, become activated in the spleen/nodes if their T-cell receptors bind to an antigen presented by an MHC molecule and they receive additional costimulation signals driving them to acquire killing (mainly CD8 ⁺ T cells) or supporting (mainly CD4 ⁺ T cells) functions;
“titer”	a measurement of the amount or concentration of a substance in a solution. For antibody titer, it refers to a measurement of how much antibody an organism has produced that recognizes a particular epitope, expressed as the inverse of the greatest dilution (in a serial dilution) that still gives a positive result;
“tetanus toxoid”	used to prevent tetanus (also known as lockjaw), which is a serious illness that causes convulsions (seizures) and severe muscle spasms that can be strong enough to cause bone fractures of the spine;
“tolerability”	the degree to which overt AEs of a drug can be tolerated by a patient;
“vaccine”	a biological preparation that activates immune system and provides active acquired immunity to a particular disease;
“valent”	in the context of vaccines, the type of microorganisms that the vaccine is designed to immunize against;
“varicella”	also known as chickenpox, an acute infectious disease caused by the first infection of the varicella zoster virus;
“vector”	an agent (such as a plasmid or virus) that contains or carries modified genetic material (such as recombinant DNA) and can be used to introduce exogenous genes into the target cells or the genome of an organism;

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“Vero cell*”	a cell line derived from renal epithelial cells isolated from an African green monkey;
“VLPs”	virus-like particles, protein complexes with molecular structures that closely resemble viruses;
“VZV”	varicella-zoster virus, one of nine herpesviruses known to infect humans that causes chickenpox (varicella) in children and herpes zoster (shingles) in adults; and
“WHO”	World Health Organization.

* The original cell line was named Vero after an abbreviation of *verda reno*, which means ‘green kidney’ in Esperanto (a constructed international auxiliary language).