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.

"AC Conjugate Vaccine"	Group A and C Meningococcal Polysaccharide Conjugate Vaccine
"Acinetobacter baumannii"	A species of Gram-negative bacteria that is a significant cause of hospital-acquired infections, particularly in intensive care units. It is known for its high level of antibiotic resistance and is classified by the WHO as a "critical" priority pathogen
"adhesion"	In microbiology, the process by which bacteria attach to host cells and surfaces, a critical first step in colonization and causing infection
"adjuvant"	Non-specific immune enhancers capable of enhancing, accelerating or prolonging the immune response to vaccine antigens
"Adjuvanted Influenza Vaccine"	Adjuvanted trivalent influenza virus split vaccine (MDCK Cells)
"Adverse Event" or "AE"	Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product, which does not necessarily have a causal relationship with the treatment
"Alhydrogel"	A proprietary aluminum hydroxide adjuvant used to enhance the immunogenicity of vaccines by facilitating the delivery of antigens to the immune system and stimulating a robust antibody response
"antibody"	A Y-shaped protein produced by the immune system's B cells that recognizes and binds to a specific antigen, helping to neutralize or eliminate pathogens
"antigen"	A substance, typically a protein or polysaccharide from a pathogen, that is recognized by the immune system and is capable of triggering an immune response
"aseptic process"	A manufacturing process conducted under sterile conditions to prevent microbial contamination of the product, crucial for injectable drugs and vaccines
"bacteremia"	The presence of viable bacteria in the bloodstream, which can lead to a life-threatening systemic infection known as sepsis
"bactericidal antibodies"	Antibodies that are capable of directly killing bacteria, often by activating the complement system

GLOSSARY OF TECHNICAL TERMS

"bacterial M protein"	A major surface virulence factor of Group A Streptococcus that inhibits phagocytosis. It is highly variable and serves as the basis for the serological classification of streptococcal strains
"bioavailability"	The proportion of a drug or other substance that enters the circulation when introduced into the body and so is able to have an active effect
"biopharmaceutical"	A medicinal product manufactured in, extracted from, or semi-synthesized from biological sources, such as cells or microorganisms
"bioreactor"	A vessel used to carry out a biological reaction, such as the large-scale cultivation of cells or microorganisms, under controlled conditions for the production of vaccines or other biologics
"bulk substance" or "drug substance"	The active ingredient of a vaccine (e.g., the purified antigen or toxoid) before it is formulated with other components into the final drug product
"Candida Als3"	Candida Agglutinin-like sequence 3, a cell-surface adhesion protein of the fungus Candida albicans. It facilitates invasion of host cells and is a key target antigen for antifungal vaccines
"carbapenem-resistant"	Refers to bacteria that have developed resistance to carbapenems, a class of last-resort antibiotics used for treating severe infections
"carrier protein"	A protein that is chemically linked (conjugated) to a polysaccharide antigen to convert it into a T-cell dependent antigen, thereby enhancing its immunogenicity, particularly in infants
"CDC"	center for disease control and prevention
"cell-mediated immunity"	An immune response that does not involve antibodies but rather involves the activation of T cells, which can directly kill infected cells or help activate other immune cells
"chemically defined culture medium"	A growth medium for cell or microbial culture in which all of the chemical components are known. It is free of animal-derived components, which enhances safety and consistency
"chimerization/chimeric protein"	A technique in genetic engineering where a single protein is created by fusing together parts (e.g., epitopes) from two or more different original proteins. This is used in vaccine design to present multiple targets to the immune system in one molecule

"Chinese Hamster Ovary cell" or "CHO cell"	An epithelial cell line derived from the ovary of the Chinese hamster, widely used in the biopharmaceutical industry for the stable, high-yield production of recombinant proteins
"chromatography"	A laboratory technique for the separation of a mixture. In vaccine manufacturing, it is a critical step for purifying antigens from other cellular components to achieve high purity
"Class 1.1", "Class 2.2", "Class 3.3" vaccine	Pursuant to the Announcement on the Publication of the Registration Classification of Biological Products and Requirements for Application Dossiers (《關於發布生物製品註冊分類及申報資料要求的通告》) issued by the NMPA on July 1, 2020, preventive biological products (vaccines) are classified for registration purposes. The relevant classifications for vaccine candidates are set out below: (i) Class 1.1 refers to innovative vaccines (創新型疫苗) that have not been marketed in the PRC or overseas and are intended for diseases for which there are no effective preventive measures available; (ii) Class 2.2 refers to improved vaccines (改良型疫苗) developed by making significant technical improvements to vaccines already marketed in the PRC or overseas, resulting in a new product with demonstrable advantages in safety, efficacy, or quality control. Such improvements include modifications to the vaccine strain/virus seed, cell substrate, manufacturing process, or dosage form (e.g., using a different expression system or cell substrate; changing the bacterial or viral strain or modifying an approved strain; modifying an approved cell substrate or target gene; refining a non-purified vaccine into a purified vaccine; or developing a component vaccine from a whole-cell vaccine); and (iii) Class 3.3 refers to vaccines that have already been marketed in the PRC (境內已上市疫苗)
"Class I vaccine"	In the PRC, a vaccine that is included in the National Immunization Program (NIP). Class I vaccines are administered on a mandatory basis, primarily to children, and are provided free of charge by the government. This contrasts with Class II vaccines, which are voluntary and self-paid
"Class II vaccine"	In the PRC, a vaccine that is administered on a voluntary basis and paid for by the recipient or their guardian, also known as a non-immunization program vaccine
"clinical trial"	A research study conducted in human subjects to evaluate the safety, immunogenicity, and efficacy of a new vaccine or drug candidate
"chemistry, manufacturing and controls" or "CMC"	A term referring to the data and processes related to the manufacturing and quality control of a drug product, which form a critical part of a regulatory submission
"combination vaccine"	A vaccine that combines antigens against two or more different diseases into a single injection

GLOSSARY OF TECHNICAL TERMS

"conjugate vaccine"	A type of vaccine created by chemically linking (conjugating) a poorly immunogenic antigen, such as a bacterial polysaccharide, to a more immunogenic carrier protein to enhance the immune response
"conserved antigen"	An antigen (or part of an antigen) that shows little to no variation across different strains or serotypes of a pathogen, making it an ideal target for a broadly protective vaccine
"contract research organization" or "CRO"	A company that provides support to the pharmaceutical and biotechnology industries in the form of research services on a contract basis
"CovR/S mutant strains"	Strains of bacteria with mutations in the CovR/S (Control of Virulence) two-component regulatory system. These mutations often result in hypervirulence due to the upregulation of the capsule and other virulence factors
"CRM197"	Cross-reacting material 197, a genetically detoxified mutant of diphtheria toxin. It is widely used as a carrier protein in conjugate vaccines to convert polysaccharide antigens into T-cell dependent antigens, thereby enhancing immunogenicity
"detoxification"	A process in vaccine manufacturing to chemically or genetically modify a bacterial toxin to eliminate its toxicity while preserving its ability to stimulate a protective immune response. The resulting protein is called a toxoid
"DMF"	Drug Master File, a submission to a regulatory containing detailed confidential information about the facilities, processes, or materials used in the manufacturing, processing, packaging, and storing of a human drug or biologic
"double-blind"	A clinical trial design in which neither the participants nor the study investigators know which participants are receiving the experimental drug and which are receiving a placebo
"Downstream Production"	The stage of biomanufacturing that occurs after the production of the bulk drug substance (upstream), which includes formulation, filling into final containers, freeze-drying, and packaging
"enteric coating"	A polymer barrier applied to oral medications that prevents their dissolution in the acidic environment of the stomach, allowing them to be released in the intestines
"epitope"	The specific part of an antigen that is recognized by the immune system, such as by an antibody or a T-cell receptor
"fermentation"	A process used in biotechnology to cultivate microorganisms or cells in a bioreactor to produce a desired product, such as a vaccine antigen

GLOSSARY OF TECHNICAL TERMS

"formulation"	The process in which the active drug substance is combined with other chemical substances (excipients), like adjuvants and stabilizers, to produce the final medicinal product
"GAS Vaccine"	Group A Streptococcus vaccine
"Glycoprotein E" or "gE"	A protein found on the surface of the Varicella Zoster Virus that is a key target for the immune response and is used as the antigen in some recombinant zoster vaccines
"Good Manufacturing Practice" or "GMP"	A system of regulations and quality assurance measures that aims to ensure that pharmaceutical products are consistently produced and controlled to the quality standards appropriate for their intended use
"Gram-negative"	A classification of bacteria that do not retain the crystal violet stain used in the Gram staining method, characterized by a complex cell wall structure that includes a protective outer membrane
"Group A Streptococcus" or "GAS"	A bacterium, also known as *Streptococcus pyogenes*, that can cause a wide range of illnesses, from pharyngitis (strep throat) to severe invasive diseases and post-infectious complications like rheumatic heart disease
"Haemophilus influenzae type b" or "Hib"	A type of bacteria that can cause severe invasive diseases, including meningitis and pneumonia, particularly in young children
"Helicobacter pylori"	A species of bacteria that colonizes the human stomach. Chronic infection is a major cause of peptic ulcers and is the strongest known risk factor for gastric cancer, leading the WHO to classify it as a Group 1 carcinogen
"herpes zoster" or "shingles"	A painful viral infection caused by the reactivation of the Varicella Zoster Virus in adults, characterized by a blistering rash
"Hib Conjugate Vaccine"	Haemophilus Influenzae Type b Conjugate Vaccine
"high-density fermentation"	An advanced fermentation technique that achieves a much higher concentration of cells per unit volume than traditional methods, leading to increased product yield
"ICU"	intensive care unit
"IgA"	Immunoglobulin A, the primary antibody class present in mucous membranes (such as the respiratory and gastrointestinal tracts), acting as a critical first line of defense against mucosal infections

GLOSSARY OF TECHNICAL TERMS

"IgG"	Immunoglobulin G, the most abundant type of antibody found in blood and extracellular fluid, responsible for long-term immunity and the neutralization of bacterial and viral pathogens
"immune evasion"	Strategies used by pathogens to avoid detection and destruction by the host's immune system
"immunogenicity"	The ability of a substance, such as an antigen or vaccine, to provoke an immune response in the body
"immunological memory"	The ability of the immune system to recognize and more rapidly and effectively respond to a pathogen that it has encountered before, providing the basis for long-term protection from vaccination
"Investigational New Drug" or "IND"	An application submitted to a regulatory authority to obtain permission to start clinical trials of a new drug or vaccine in humans
"influenza"	A contagious respiratory illness caused by influenza viruses that infect the nose, throat, and sometimes the lungs
"in-process quality control"	Tests and checks performed during the manufacturing process to monitor and, if necessary, adjust the process to ensure that the intermediate and final product will conform to its specifications
"IsdB"	Iron-regulated surface determinant B, a surface protein on Staphylococcus aureus involved in acquiring iron from host hemoglobin. It is a target antigen for vaccines aiming to deprive the bacteria of essential iron
"lyophilized"	Freeze-dried; a process of dehydration at low temperature used to preserve perishable materials or make them more convenient for transport. Lyophilized products are reconstituted with a liquid diluent before use
"MDCK cell"	Madin-Darby Canine Kidney cell, derived from the kidney of a dog, used as a cell culture platform for the production of certain viral vaccines, such as influenza vaccines
"meningococcal disease"	A serious bacterial infection caused by Neisseria meningitidis, which can lead to meningitis and sepsis
"meningococcal vaccine"	A type of vaccine designed to protect against infections caused by meningococcal disease. These vaccines work by inducing immune responses against specific meningococcal serogroups and may use different platforms, such as polysaccharide, conjugate, or protein-based formulations, to prevent invasive meningococcal disease

GLOSSARY OF TECHNICAL TERMS

"methicillin-resistant Staphylococcus aureus" or "MRSA"	A strain of Staphylococcus aureus that is resistant to methicillin and other common antibiotics
"mHIN2"	A genetically modified recombinant protein derived from Haemophilus influenzae, used as a vaccine antigen or carrier protein to elicit a specific immune response
"mHIa"	A genetically detoxified mutant form of alpha-hemolysin (α\alphaα-toxin), a pore-forming toxin produced by Staphylococcus aureus
"MntC"	Manganese transport protein C, a highly conserved surface protein involved in manganese acquisition by Staphylococcus aureus
"monovalent vaccine"	A vaccine that is designed to immunize against a single antigen or a single microorganism
"mSEB"	A genetically modified, non-toxic form of Staphylococcal Enterotoxin B, a superantigen produced by Staphylococcus aureus
"mucosal immunity"	The immune response that occurs at mucosal membranes of the intestines, the urogenital tract, and the respiratory system, providing a first line of defense against pathogens entering the body
"multivalent vaccine"	A vaccine designed to immunize against two or more strains or serotypes of the same microorganism
"NDA" or "New Drug Application"	The formal application submitted to a regulatory authority to request approval to market a new drug or vaccine
"Opsonophagocytic Activity" or "OPA Assay"	A laboratory test that measures the functional ability of vaccine-induced antibodies to help immune cells (phagocytes) engulf and kill bacteria
"opportunistic pathogen"	A microorganism that does not ordinarily cause disease in a healthy individual but can cause infection in individuals with weakened immune systems
"oral capsule"	A form of oral medication where the drug is enclosed in a shell. It can be designed with special coatings (e.g., enteric coating) to control where the drug is released in the digestive system
"P2 epitopes"	Specific peptide sequences, often derived from tetanus toxoid, used as helper T-cell epitopes to augment the immunogenicity of peptide-based vaccines and ensure a robust immune response

GLOSSARY OF TECHNICAL TERMS

"Pan-DR"	Pan-DR epitope (PADRE), a universal helper T-cell epitope designed to bind to a broad range of HLA-DR molecules, used in vaccines to enhance the immune response across a genetically diverse human population
"pathogen"	A bacterium, virus, or other microorganism that can cause disease
"perioperative"	The period of time extending from when a patient goes into the hospital for surgery until the time the patient is discharged; in the context of vaccination, refers to immunization administered shortly before or around the time of surgery
"pertussis" or "whooping cough"	A highly contagious respiratory tract infection caused by the bacterium Bordetella pertussis
"Phase I clinical trial"	The first stage of clinical testing in humans, primarily designed to evaluate the safety, tolerability, and dosage of a new drug or vaccine
"Phase Ia clinical trial"	The initial stage of Phase I clinical trials, typically conducted in a small number of healthy volunteers to evaluate the safety, tolerability, and pharmacokinetics of an investigational drug or vaccine
"Phase Ib clinical trial"	A subsequent stage of Phase I clinical trials, often conducted to assess safety, tolerability, and preliminary immunogenicity or efficacy in a specific patient population or expanded cohort
"Phase II clinical trial"	The second stage of clinical testing conducted in a larger group of patients to assess the preliminary efficacy and immunogenicity of the drug or vaccine and to further evaluate its safety
"Phase III clinical trial"	A large-scale, pivotal clinical trial conducted in a large patient population to definitively establish the efficacy and safety of a drug or vaccine in comparison to a placebo or standard treatment, required for regulatory approval
"Phase IV clinical trial"	Post-marketing studies conducted after a drug or vaccine has been approved by regulatory authorities, intended to monitor long-term safety, efficacy, and potential adverse reactions in the general population
"pharmacovigilance"	The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem
"placebo"	An inactive substance or treatment that looks the same as, and is given the same way as, an active drug or treatment being tested in a clinical trial

"polysaccharide"	A large carbohydrate molecule made up of many smaller sugar units. The outer capsules of many bacteria are made of polysaccharides, which are often used as antigens in vaccines
"post-exposure prophylaxis"	Preventive medical treatment started immediately after exposure to a pathogen (such as through a wound) in order to prevent infection from occurring
"postherpetic neuralgia"	A common complication of shingles, characterized by chronic nerve pain that persists in the area of the rash after the blisters have healed
"preclinical"	The stage of research that begins before clinical trials, during which important feasibility, iterative testing, and drug safety data are collected, typically in laboratory and animal studies
"pre-filled syringe" or "PFS"	A disposable syringe that is supplied already loaded with the substance to be injected, offering convenience and improved dosing accuracy
"Pseudomonas aeruginosa"	An opportunistic bacterium that is a common cause of hospital-acquired infections. Carbapenem-resistant strains are classified by the WHO as a "critical" priority pathogen
"QS-21"	A potent saponin-based adjuvant derived from the bark of the Quillaja saponaria tree, capable of stimulating both strong antibody (humoral) and cell-mediated immune responses
"Quadrivalent Influenza Vaccine"	Quadrivalent influenza virus split vaccine (MDCK Cells)
"quadrivalent vaccine"	A vaccine designed to protect against four different strains or serotypes of a virus or bacterium
"Quality by Design"	A systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management
"randomized"	A feature of a clinical trial in which participants are assigned by chance to separate groups that compare different treatments
"recombinant protein"	A protein produced by host cells (such as CHO cells or E. coli) that have been modified through genetic engineering to express a gene from another organism
"recombinant vaccine"	A vaccine produced using recombinant DNA technology, typically by inserting the gene that codes for a specific antigen into a host cell system to produce large quantities of that antigen

GLOSSARY OF TECHNICAL TERMS

"reverse vaccinology"	A method of vaccine development that begins with the analysis of a pathogen's genome to identify potential antigens, rather than starting with the whole pathogen
"rABV"	recombinant Acinetobacter baumannii vaccine
"rFPAV"	Recombinant four-antigen Pseudomonas aeruginosa vaccine
"rFSAV"	Recombinant five-antigen Staphylococcus aureus vaccine
"rHPV"	Oral recombinant Helicobacter pylori vaccine (E. Coli)
"serotype"	A distinct variation within a species of bacteria or virus, distinguished by the specific antigens on its surface
"serum-free media"	A cell culture medium that does not contain animal serum (such as fetal bovine serum), which reduces variability and eliminates the risk of contamination from serum-derived agents
"SpA"	Staphylococcal protein A, a cell wall-anchored protein of Staphylococcus aureus that binds to the Fc region of antibodies (IgG), thereby helping the bacteria evade immune recognition and phagocytosis
"influenza split vaccine"	A type of inactivated influenza vaccine produced by disrupting the virus particle with a chemical agent (detergent), resulting in a vaccine containing viral surface antigens and other viral components
"SpyCEP protein"	Streptococcus pyogenes cell envelope proteinase, a virulence factor that cleaves interleukin-8 (IL-8) to impair the recruitment of neutrophils. It is a vaccine antigen candidate included to neutralize this immune-evasion mechanism
"Staphylococcus aureus"	A common bacterium that is a leading cause of a wide range of infections, from minor skin infections to life-threatening diseases like pneumonia and sepsis
"subunit vaccine"	A vaccine that includes only specific, purified components (subunits) of a pathogen, such as proteins or polysaccharides, which is designed to improve safety and reduce adverse reactions
"superbug"	A colloquial term for a strain of bacteria that has become resistant to multiple antibiotic drugs
"Superbug List"	A list of antimicrobial-resistant pathogens classified by WHO as priority organisms that poses significant threats to global public health
"superbug vaccine candidates"	rFSAV, rHPV, rFPAV, rABV and GAS Vaccine

GLOSSARY OF TECHNICAL TERMS

"suspension culture"	A method of cell culture in which cells are grown suspended in a liquid nutrient medium, which is suitable for large-scale production in bioreactors
"T cell"	A type of white blood cell that plays a central role in the adaptive immune response. T cells can directly kill infected cells or help activate other immune cells like B cells
"tetanus"	A serious disease of the nervous system caused by a toxin-producing bacterium, Clostridium tetani, which causes severe muscle spasms, also known as "lockjaw"
"tetanus toxoid" or "TT"	The inactivated, non-toxic form of the tetanus toxin used as the antigen in tetanus vaccines and as a carrier protein in some conjugate vaccines
"toxoid"	A bacterial toxin that has been modified to be non-toxic but still retains its ability to stimulate an immune response, making it suitable for use as a vaccine antigen
"Trivalent Influenza Vaccine"	Trivalent influenza virus split vaccine (MDCK Cells)
"trivalent vaccine"	A vaccine designed to protect against three different strains or serotypes of a virus or bacterium
"unblinding"	The process in a double-blind clinical trial where the identity of the treatment given to each participant is revealed to the investigators, typically after the clinical trial has concluded
"upstream production"	The initial stage of biomanufacturing where cells or microorganisms are cultivated in bioreactors to produce the bulk drug substance (the active ingredient)
"vaccine"	A biological preparation that provides active acquired immunity to a particular infectious disease by stimulating the body's immune system
"Varicella Zoster Virus" or "VZV"	The herpesvirus that causes chickenpox (varicella) as a primary infection and can reactivate later in life to cause shingles (herpes zoster)
"virulence"	The degree of pathogenicity of a microorganism; its ability to cause disease. Vaccine development often involves targeting key virulence factors
"WHO" or "World Health Organization"	A specialized agency of the United Nations responsible for international public health