GLOSSARY

This glossary contains certain technical terms used in this document in connection with us and our business. Such terms and their meaning may not correspond to standard industry definitions or usage.

"antibody" or "Ab"	large, Y-shaped protein produced mainly by plasma cells that is used by the immune system to identify and neutralize pathogens such as bacteria and viruses
"ACC"	antibody-chelator conjugate
"antibody drug conjugates" or "ADCs"	an emerging class of highly potent biopharmaceutical drugs designed as a targeted therapy combining the specific targeting capabilities of monoclonal antibodies with the cancer-killing ability of cytotoxic drugs for the treatment of cancer
"AOC"	antibody-oligonucleotide conjugate
"assay" or "bioassay"	an investigative analytical process in medicine, pharmacology or biology that aims to identify either the qualitative or quantitative presence or function of the analytical target, which can be a drug or biochemical substance or a cell in an organism or organic sample
"bioconjugate"	complex molecule engineered by covalently attaching two or more biological components in order to achieve improved targeting, efficacy and pharmacokinetics for therapeutic applications
"biohazardous"	of or relating to the health risk posed by the possible release of a pathogen into the environment
"biologics"	a subset of pharmaceuticals that are composed of a mixture of sugars, proteins, nucleic acids or complex compositions and may be made from biological sources
"bispecific antibody"	artificial protein that is composed of fragments of two different monoclonal antibodies and consequently binds to two different types of antigen
"Biologics License Application" or "BLA"	a request for permission to introduce, or deliver for introduction, a biologic product for commercialization in a specific jurisdiction
"chemistry, manufacturing and controls" or "CMC"	an important and detailed section in a dossier to support clinical studies conducted in human and marketing applications

"clinical trial"	a type of research carried out on human that studies new tests and treatments and evaluates their effects on human health outcomes
"conjugation"	the joining of two compounds
"contract research, development and manufacturing organization" or "CRDMO"	a company that mainly provides discovery, CMC and manufacturing services in the pharmaceutical and/or biotech industry
"contract testing, development and manufacturing organization" or "CTDMO"	a company that mainly provides testing, CMC and manufacturing services in the pharmaceutical and/or biotech industry
"Current Good Manufacturing Practice" or "cGMP"	regulations enforced by the FDA on pharmaceutical and biotech firms to ensure that the products produced meet specific requirements for identity, strength, quality and purity
"drug product formulation"	the process in which different chemical substances, including the active drug, are combined to produce a final medicinal product
"drug product" or "DP"	a dosage form that contains an active drug ingredient
"drug substance" or "DS"	an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient
"drug-to-antibody ratio" or "DAR"	refers to the average number of drug molecules that are attached to each antibody molecule
"enzyme-linked immunosorbent assay" or "ELISA"	a commonly used laboratory test that measures the concentration of an antigen in a sample
"FDA"	the U.S. Food and Drug Administration
"fill and finish"	the last process in the production of pharmaceuticals that involves the filling of the bottle and any post-filling processes
"Good Laboratory Practices" or "GLP"	a quality system of management controls for research laboratories and organizations to try to ensure the uniformity, consistency, reliability, reproducibility, quality and integrity of chemical and pharmaceuticals non-clinical safety tests
"global ADC outsourcing services market"	the outsourcing services market for both ADC and broader bioconjugates

"HPLC"	High Performance Liquid Chromatography, a form of column chromatography that pumps a sample mixture in a solvent at high pressure through a column with chromatographic packing material
"in vitro"	Latin for "in glass"; studies in vitro are conducted using components of an organism that have been isolated from their usual biological surroundings, such as microorganisms, cells or biological molecules
"in vivo"	Latin for "within the living"; studies in vivo are those in which the effects of various biological entities are tested on whole, living organisms as opposed to a partial or dead organism, or those done in vitro ("within the glass"), i.e., in a laboratory environment using test tubes, petri dishes etc.
"IND"	Investigational New Drug, an application submitted to the FDA or the NMPA to seek permission or no objection to ship unapproved, experimental drug or biologic agents across jurisdictions (usually to clinical investigators) for use in clinical studies before a marketing application for the drug has been approved
"integrated projects"	post-discovery projects (i.e., in preclinical and subsequent stages) that involve clinical or commercial manufacturing
"linker"	a chemical group that covalently attaches the payload to the biomolecule in a bioconjugate, serving as a flexible tether between the two components
"lot release testing"	the process of evaluating each batch of a product before giving approval for its release onto the market
"McMMAE"	Maleimidocaproyl-monomethylauristatin E
"McMMAF"	Maleimidocaproyl-monomethylauristatin F
"MMAE"	Monomethyl auristatin E
"modality"	a type of treatment for a disease or medical condition
"molecule"	an electrically neutral group of two or more atoms held together by chemical bonds

"monoclonal antibody" or "mAb"	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
"NMPA"	National Medical Products Administration (國家藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局) from 2013 to 2018 and the State Food and Drug Administration (國家食品藥品監督管理局) from 2003 to 2013
"occupational exposure band" or "OEB"	a process that is used to quickly and accurately assign chemicals into specific categories (bands), which correspond to a range of exposure concentrations designed to protect worker health. The OEB system typically ranges from OEB1 (least hazardous) to OEB5 (most hazardous)
"oncology"	the study and treatment of tumors
"outsourcing rate"	the outsourcing rate is calculated by dividing the size of the relevant outsourcing services market of a modality by the total outsourceable research, development and manufacturing expenses on that modality
"payload"	the component that elicits the desired therapeutic response, which is attached to the antibody by a linker and is released at the desired target
"payload-linker"	payload, linker and/or payload-linker, which combines both the payload and the linker, as the context requires. Conjugation, which typically refers to the combination of the antibody intermediate and payload-linker and is one of the most important steps in generating bioconjugates, is a separate step from combining the payload and linker molecules
"PCC"	preclinical candidate
"PDC"	peptide-drug conjugate
"PMDA"	the Pharmaceuticals and Medical Devices Agency of Japan
"process performance qualification" or "PPQ"	a part of the validation process which ensures that a certain process, system, or method used in production maintains the desired level of compliance at all stages

"PROTAC"	proteolysis targeting chimera, a molecule that induces selective intracellular proteolysis
"preclinical"	of or relating to a stage preceding clinical stage
"R&D"	research and development
"stability studies"	studies on the capability of a drug in a specific container/closure system to remain within its physical, chemical, microbiological therapeutic and toxicological specification
"synthesis"	the production of chemical compounds by reaction from simpler materials
"therapeutic window"	the dose range of a drug that provides safe and effective therapy