
GLOSSARY OF TECHNICAL TERMS

This glossary contains explanations of certain technical terms used in this document in connection with our Company and its business. Such terminology and meanings may not correspond to standard industry meanings or usages of those terms.

“ActRIIA”	activin receptor type IIA
“ADT”	androgen deprivation therapy
“AEs”	adverse events, any untoward medical occurrences in a patient or clinical investigation subject administered a drug or other pharmaceutical product during clinical trials which do not necessarily have a causal relationship with the treatment
“aHSC”	activated hepatic stellate cells
“AKT”	a serine/threonine protein kinase with 3 isoforms (AKT1, AKT2 and AKT3) that participate in multiple pathways regulating several cellular processes, including survival, proliferation, tissue invasion, and metabolism
“antibody (Ab)”	also known as an immunoglobulin (Ig), a protein used by the immune system to recognize and bind an antigen
“antigen”	the substance that is capable of stimulating an immune response, specifically activating lymphocytes, which are the body’s infection-fighting white blood cells
“apoptosis”	a form of programmed cell death in which a programmed sequence of events leads to the elimination of cells
“ATP”	adenosine triphosphate, an organic compound
“AUC”	area under curve, a parameter of systemic exposure
“AR inhibitor”	anti-androgen receptor inhibitor
“BID”	twice-daily administration
“BT474”	a breast cancer cell line, characterized by the overexpression of HER2 and ER

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“BRAF”	a protein kinase involved in directing cell growth and shown to be mutated in some human cancers
“BRCA”	proteins involved in gene damage repair, including BRCA1 and BRCA2
“CDK”	cyclin-dependent kinases, a family of protein kinases regulating the cell cycle, also involved in regulating transcription, mRNA processing, and the differentiation of nerve cells
“CDMO”	contract development and manufacturing organization, a company that develops and manufactures drugs for other pharmaceutical companies on a contractual basis
“cGCP”	current good clinical practice, an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans
“cGLP”	current good laboratory practice, a quality system of management controls for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical (including pharmaceuticals) non-clinical studies
“cGMP”	current good manufacturing practice, containing minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have
“chemotherapy”	a category of cancer treatment that uses one or more anti-cancer cytotoxic agents
“clinical trial/study”	a research study for validating or finding the therapeutic effects and side effects of test drugs in order to determine the therapeutic value and safety of such drugs
“CMC”	chemistry, manufacture and control

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“CMO”	contract manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services of drug manufacturing
“cohort”	a group of patients as part of a clinical study who share a common characteristic or experience within a defined period and who are monitored over time
“combination therapy”	treatment in which a patient is given two or more drugs (or other therapeutic agents) for a single disease
“CR”	complete response, the disappearance of all signs of cancer in response to treatment
“CRO”	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“CSCO Guideline”	The Chinese Society of Clinical Oncology Guideline
“CYP17A1”	cytochrome P450 family 17 subfamily A member 1, an enzyme of the hydroxylase type that in humans is encoded by the CYP17A1 gene
“CYP11B2”	cytochrome P450 family 11 subfamily B member 2
“DOR”	duration of response, the length of time that a tumor continues to respond to treatment without the cancer growing or spreading
“EC ₅₀ ”	half maximal effective concentration, referring to the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum after a specified exposure time
“FFS”	failure-free survival
“fibrosis”	a condition marked by increase of interstitial fibrous tissue

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“GMP”	good manufacturing practice, the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of products
“Grade – in relation to AE”	term used to refer to the severity of adverse events according to Common Terminology Criteria for Adverse Events (CTCAE) v4.03, using Grade 1, Grade 2, Grade 3, etc.
“HHT”	hereditary hemorrhagic telangiectasia
“HR+/HER2- breast cancer”	the most common type of breast cancer with overexpression of HR and without overexpression of HER2
“IC ₅₀ ”	concentration at half maximal inhibition, a measure of the potency of a substance in inhibiting a specific biological or biochemical function
“ICI”	immune checkpoint inhibitor
“immuno-oncology”	a type of immunotherapy that is specifically targeted to fight cancer
“immunology”	study of immune systems in an organism in biological science
“immunotherapy”	use of the immune system to treat disease
“ <i>in vivo</i> ”	studies in which the effects of various biological entities are tested on whole, living organisms, usually animals, including humans, and plants, as opposed to a tissue extract or dead organism
“ <i>in vitro</i> ”	studies that are performed with microorganisms, cells, or biological molecules outside their normal biological context
“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

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“IV”	intravenous injection, an injection of a medication or another substance into a vein and directly into the bloodstream
“Ki* values”	inhibition constant, the dissociation constant for an enzyme inhibitor complex
“lines of treatment”	the order in which different therapies are given to patients as their disease progresses, such as first-line, second-line, third-line etc.
“liver cirrhosis”	a chronic liver disease marked by fibrous thickening of tissue
“mAb”	monoclonal antibody, an antibody generated by identical immune cells that are all clones of the same parent cell
“mCRPC”	metastatic castration resistant prostate cancer
“metastatic”	in reference to any disease, including cancer, disease-producing organisms or of malignant or cancerous cells transferred to other parts of the body by way of the blood or lymphatic vessels or membranous surfaces
“mHSPC”	metastatic hormone-sensitive prostate cancer
“MOA”	mechanism of action, specific mechanism producing its pharmacological effect
“monotherapy”	therapy that uses a single drug to treat a disease or condition
“MTD”	maximum tolerated dose, the highest dose of a drug or treatment that does not cause unacceptable side effects
“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
“NAFLD”	non-alcoholic fatty liver disease
“NASH”	non-alcoholic steatohepatitis, liver inflammation and damage caused by accumulation of fat in the liver

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“NCCN Guideline”	The National Comprehensive Cancer Network Guideline
“NDA”	new drug application, a process required by an regulatory authority to approve a new drug for sale and marketing
“NSCLC”	non-small-cell lung cancer, any carcinoma (as an adenocarcinoma or squamous cell carcinoma) of the lungs that is not a small-cell lung carcinoma
“NGS”	next generation sequencing, a massively parallel sequencing technology that offers ultra-high throughput, scalability, and speed
“ORR”	overall response rate, the proportion of patients who have a partial or complete response to therapy
“OS”	overall survival, a length of time that a patient with a specific disease is still alive, used as a measurement of a drug’s effectiveness
“paclitaxel”	a chemotherapy medication used to treat a number of types of cancer, includes ovarian cancer, esophageal cancer, breast cancer, lung cancer, Kaposi’s sarcoma, cervical cancer, and pancreatic cancer
“PARP”	poly (ADP-ribose) polymerase, a family of proteins involved in a number of cellular processes, such as DNA repair, genomic stability, and programmed cell death
“PD”	pharmacodynamics, the branch of pharmacology concerned with the effects of drugs and the mechanism of their action
“PD-1”	programmed death-1, an immune checkpoint receptor expressed on T cells, B cells and macrophages, acting to turn off the T cell mediated immune response as part of the process that stops a healthy immune system from attacking other pathogenic cells in the body
“PD-L1”	programmed death ligand-1, a protein on the surface of a normal cell or a cancer cell that attaches to PD-1 on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell

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“PDX”	patient derived xenografts, a model of cancer where the tissue or cells from a patient’s tumor are implanted into an immune-deficient or humanized mouse
“PFS”	progression-free survival, the length of time during and after the treatment of a disease, such as cancer, that a patient lives without the disease getting worse. In a clinical trial, measuring the progression-free survival is one way to see how well a new treatment works
“PSOC”	platinum-sensitive ovarian cancer
“Phase I clinical trial(s)”	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 efficacy
“Phase Ia clinical trial(s)”	study in which dose escalation is tested on the healthy human subjects or patients to primarily assess safety, dosage tolerance, and PK/PD at different dose levels
“Phase Ib clinical trial(s)”	study in which dose expansion is tested on the healthy human subjects or patients to primarily assess safety, dosage tolerance and PK/PD at different dose levels
“Phase II clinical trial(s)”	study in which a drug is administered to a limited patient population to preliminarily evaluate the efficacy of the product for specific targeted diseases, to identify possible adverse effects and safety risks, and to determine optimal dosage
“Phase III clinical trial(s)”	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 labeling of the product
“PO”	(medication taken) by mouth
“PI3K”	phosphoinositide 3 kinase, an important signaling node for many cellular functions such as growth control, metabolism and translation initiation

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“PI3KCA”	PI3K catalytic subunit alpha
“PK”	pharmacokinetics, the study of the bodily absorption, distribution, metabolism, and excretion of drugs, which, together with pharmacodynamics, influences dosing, benefit, and adverse effects of the drug
“PKA”	protein kinase A, cAMP-dependent protein kinase
“PKC”	protein kinase C, a serine/threonine protein kinase, controlling function of other proteins through phosphorylation
“PKC θ ”	protein kinase C θ isoform
“PKC δ ”	protein kinase C δ isoform
“PKC η ”	protein kinase C η isoform
“PKC β 1”	protein kinase C β 1 isoform
“PKG”	protein kinase G or cGMP-dependent protein kinase, a serine/threonine protein kinase activated by cGMP
“PKG1 α ”	cGMP-dependent protein kinase 1, alpha isozyme
“PKG1 β ”	cGMP-dependent protein kinase 1, beta isozyme
“placebo”	a treatment or preparation with no specific pharmacological activity
“PR”	partial response, an at least 30% but less than 100% decrease in the size of a tumor or in the extent of cancer in the body in response to treatment per RESIST criteria
“PRAS40”	proline-rich Akt substrate of 40 kDa
“pre-clinical studies”	pre-clinical studies testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether the drug is ready for clinical trials
“primary endpoint”	the main or most important outcome at the end of a study to determine whether a new drug or treatment works

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“PROC”	platinum resistant ovarian cancer
“PROTAC”	proteolysis targeting chimera
“proof of concept (POC)”	an early stage of drug development used to demonstrate that a drug is likely to be successful
“PSA”	prostate specific antigen, a protein that may be present with elevated levels in a prostate cancer or other disease patient, which is commonly used as an efficacy indicator of anti-prostate cancer drugs
“PTEN”	phosphatase and tensin homolog deleted on chromosome ten, a negative regulator of PI3K
“p70S6K”	p70S6 kinase, a protein kinase encoded by the RPS6KB1 gene in humans
“QD”	once-daily administration
“refractory”	a disease that is resistant at the beginning of treatment or becomes resistant during treatment
“registrational clinical trial”	a clinical trial study to demonstrate clinical efficacy and safety evidence to support the marketing approval of a drug
“ROCK1”	a protein serine/threonine kinase, also known as rho-associated, coiled-coil-containing protein kinase 1
“RP2D”	recommended Phase II dose
“RSK”	ribosomal s6 kinase, a family of protein kinases involved in signal transduction
“SCID mice”	severe combined immunodeficient mice, often used in the research of human disease
“SD”	stable disease, in oncology, indicating a cancer that is neither decreasing at least 30% nor increasing at least 20% in the size of a tumor or in the extent of cancer in the body in response to treatment

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“standard of care (SOC)”	treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals
“TAA”	tumor associated antigen, a portion of intracellular molecules expressed on the cell surface that allows large proteins in immune system cells to identify compatible or foreign proteins to help the body make an immune response against cancer cells or to help boost the body’s immune system to kill more cancer cells
“TGF”	transforming growth factor, a family of proteins involved in regulating and mediating processes at the cellular level
“TGI”	tumor growth inhibition
“TNBC”	triple-negative breast cancer, any breast cancer that tests negative for estrogen receptors, progesterone receptors, and excess HER2
“TRAE”	treatment-related adverse event, undesirable events not present prior to medical treatment or an already present event that worsens in intensity or frequency following the treatment
“translational research”	the process by which the results of research done in the laboratory are used to develop new ways of diagnosis and treatment