

GLOSSARY CONTINUED

pharmacovigilance The scientific collection and evaluation of information from healthcare providers and patients relating to the adverse effects of medicines.

phase I The phase of clinical research where a new drug or treatment is tested in small groups of people (twenty to eighty) to check that the drug can achieve appropriate concentrations in the body and, determine a safe dosage range, and identify side effects. This phase includes healthy volunteer studies.

phase II This phase of clinical research includes the controlled clinical activities conducted to evaluate the effectiveness of the drug in patients with the disease under study and to determine the common short-term side effects and risks associated with the drug. Phase II studies are typically conducted in a relatively small number of patients (usually no more than several hundred).

phase III This phase of clinical research is performed to gather additional information about effectiveness and safety of the drug, often in a comparative setting, to evaluate the overall benefit/risk profile of the drug. Phase III studies usually include between several hundred and several thousand patients.

PIE Pharmaceuticals in the environment.

placebo In clinical trials, an inert substance identical in appearance to the substance being tested, also known as a sugar pill.

platelets The blood cells that form blood clots.

poly-ADP-ribose polymerase (PARP) An enzyme critical to the repair of damaged cells and maintenance of cellular energy.

positron emission tomography (PET) A highly specialised imaging technique that uses short-lived radioactive substances to produce three-dimensional coloured images of those substances functioning within the body. These images are called PET scans.

post-marketing surveillance (PMS) The systematic detection and evaluation of adverse reactions occurring in association with pharmaceutical products once these are available in the marketplace.

pre-clinical studies Studies conducted before a drug is tested in human subjects, and which support and help establish boundaries for safe use of the drug in subsequent phase I studies.

pressurised metered dose inhaler (pMDI) An aerosol inhaler/puffer device for delivering medicine directly into the lungs.

primary care The medical care that a patient receives upon first contact with the healthcare system, before referral elsewhere within the system.

profit before tax Operating profit, plus finance income, less finance expense.

prolactin The hormone that stimulates milk production after childbirth.

proof of concept Proof of concept provides clinical confirmation that an investigational product possesses a desired pharmacological effect in patients with the disease of interest. This can be achieved after a positive placebo-controlled study or dose-response study using a validated surrogate variable or the final clinical outcome variable. Proof of concept also includes establishing a limited dose range to be used in the subsequent confirmatory studies.

proof of principle Proof of principle is achieved when an intended pharmacological effect results in an expected change in a relevant biomarker in a dose range, which does not cause any major unwanted effects. Proof of principle therefore provides the first measurable evidence that an investigational product might work in humans. Proof of principle is normally demonstrated in a limited number of subjects with the disease of interest or in healthy volunteers when a relevant model exists.

prophylaxis or prophylactic therapy A therapy or measure used to prevent disease.

proton pump inhibitor (PPI) A medicine that reduces the production of acid in the stomach.

psychiatry The study, prevention and treatment of mental illnesses and emotional and behavioural problems.

qui tam action (in the US) An action brought under a statute that allows a private person to sue for a penalty, part of which the government or some specified public institution will receive.

R&D Research and development.

reflux oesophagitis A condition in which acidic fluid is regurgitated from the stomach into the oesophagus.

respiratory Relating to or affecting breathing or the organs used to breathe.

respiratory syncytial virus (RSV) A virus that attacks the mucous membranes of the human respiratory tracts, including the nose, throat and air passages.

RET-kinase A receptor-tyrosine kinase which is normally involved in maturation of a variety of tissues, including the nervous system and kidney. It is sometimes mutated and has an abnormal function in certain types of thyroid cancer.

rheumatoid arthritis (RA) Joint inflammation in which the joints become painful, swollen, stiff, and in severe cases, deformed.

ribonucleic acid (RNA) A nucleic acid molecule containing ribose. RNA plays a key role in many biological processes, including translating genetic information from DNA into proteins.

ribosome A large complex intracellular molecule that synthesises protein.

ribosome display A technique used to create proteins that can bind a desired atom, ion or molecule.

ROW Rest of the world.

schizophrenia A psychiatric condition in which the patient suffers impairment of their perception of reality.

second-line therapy Treatment administered after the failure of, or in addition to, first-line therapy.

Securities and Exchange Commission (SEC) US governmental agency that regulates the securities industry/stock market.

SEK, kronor, krona References to Swedish currency.

sepsis A life-threatening condition resulting from uncontrolled severe infection.

SG&A costs Selling, general and administrative costs.

SHE Safety, health and the environment.

small molecule A general term used to describe pharmaceutical R&D using chemistry and chemical methods and materials to discover and develop new medicines. Chemical molecules are small compared with biological molecules.

specialist care The medical care the patient receives after being referred by the primary care provider.

SR Sustained release.

SSE Stockholm Stock Exchange.

statin A class of drugs that alter cholesterol levels in the blood.

sterling, £, GBP, pence or p References to the currency of the UK.

supplemental new drug application (sNDA) An application made to the US Food and Drug Administration to seek approval to market a marketed drug for another indication.

systemic lupus erythematosus (SLE) A disease of the immune system (the system that prevents and fights infection).

target product profile (TPP) Statement of the essential attributes required for a specific drug to be a clinically and commercially successful product, which can form the basis for commercial evaluation and guide Discovery and Development activities.

thrombosis The formation of blood clots.

toxicology The study of poisons.

triglycerides The major form of fat that comes from the food we eat as well as from being produced by the body.

TSR Total shareholder returns.

Type 2 diabetes An illness caused by the body being resistant to insulin.

UK The United Kingdom of Great Britain and Northern Ireland.

UK Combined Code Guidance that sets out standards of good practice in corporate governance for the UK.

urology Relating to the structure, functioning and disorders of the urinary tract.

US The United States of America.

US dollar, US\$, USD or \$ References to the currency of the US.

vascular endothelial cell growth factor (VEGF) A growth factor which promotes the growth of new blood vessels.

World Health Organization (WHO) The United Nations' specialised agency for health.

XR Extended release.

Zollinger-Ellison syndrome A rare gastric acid disorder.