

Cubist

Glossary of Terms

CUBIST
PHARMACEUTICALS

Acute Care: Short-term medical treatment, usually in a hospital, for patients having an abrupt onset (acute) illness or injury or recovering from surgery (Acute often also connotes an illness that is of short duration, rapidly progressive, and in need of urgent care)

AE: Adverse event

Amino Acid: Any one of 20 organic compounds containing an amino (NH₂) group and a carboxyl (COOH) group, occurring naturally in plants and animals; the building blocks of proteins

aNDA: Abbreviated New Drug Application

Antibiotic: A substance produced by microorganisms that has the capacity to inhibit the growth of or to destroy bacteria

Antibiotic Resistance: The ability of bacteria (or other microorganisms) to withstand an antibiotic to which they were once sensitive

Antibiotic Susceptibility: The ability of bacteria and other microorganisms to be affected by an antibiotic *in vitro*

Antiinfective: An agent that counteracts infection; includes both bacterial and viral infection

Antimicrobial: An agent that destroys bacteria and/or fungi or suppresses their multiplication or growth

API: Active Pharmaceutical Ingredient

Assay: Determination of the purity of a substance or the amount of any particular component of a mixture; a laboratory test performed to measure the activity of a substance against a certain target

Bacteremia: The presence of bacteria in the blood

Bacteria: Prokaryotic cells; a generic name for any non-spore forming, rod-shaped microorganism

Bactericidal: Able to kill bacteria

Bacteriostatic: Able to inhibit growth of bacteria

CAP: Community-acquired pneumonia

CDAD: *Clostridium difficile*-associated disease (also *C. difficile*, *C. Diff*)

Catheter-related Bacteremia: Bloodstream infection that is thought to be associated with a temporary or permanent intravascular catheter

CORESM: (CUBICIN Outcomes Registry & Experience): Cubist's retrospective, longitudinal, multicenter registry program designed to collect information on patients who have received CUBICIN therapy

CPK: Creatine phosphokinase - an enzyme that is contained in skeletal muscle, smooth muscle and cardiac muscle.

CUBICIN: Daptomycin-for-injection

cSSTI: Complicated skin and soft tissue infection (also cSSSI)

cSSSI: Complicated skin and skin structure infection (also CSST)

cUTI: Complicated urinary tract infection

Daptomycin: A novel lipopeptide antibiotic

Directed Biosynthesis: A process by which new substances created through the manipulation of genetic pathways

Dual Antibody Compound: A therapeutic biological consisting of two distinct antibodies that bind to different epitopes on the same molecule.

Efficacy: Strength or effectiveness, the ability of a drug to control or cure an illness

Endocarditis: Infection and inflammation of the heart's inner lining (endocardium). It is most common in patients who have a damaged, diseased, or artificial heart valve (also IE)

Left-sided Endocarditis: IE involving the mitral or aortic valve (also LIE)

Right-sided Endocarditis: IE involving only the tricuspid or pulmonic valve (also RIE)

Enterococcus: Gram-positive bacteria normally found in the feces of people and many animals

Enzymes: Proteins produced by living organisms that function as biochemical catalysts

Epitope: A site on an antigen recognized by antibody

FAS123 (R): Requires a company to estimate the fair value of equity awards on the date of grant using an option pricing model and spread the expense over the 'requisite service period' which is typically the vesting period. Cubist was required to comply with this standard in Q1 2006

FDA: Food & Drug Administration; the government agency responsible for regulating the food and drug industries, including the commercial approval of pharmaceuticals

Fermentation: Is the simultaneous growth of a micro-organism along with production of a useful product (ie: antibiotic) in a complex medium

Formulary: The list of drugs that a hospital or insurance plan makes available to physicians to treat patients, sometimes without requiring additional approval before processing

Functional Genomics: Science related to the discovery and definition of the function of genes

Fungi: Eukaryotic cells, either filamentous, molds, or unicellular yeasts

Genomics: Science pertaining to the study of the complete set of hereditary factors or genes

GISA: Glycopeptide-Intermediate *Staphylococcus aureus*

Gram-positive Bacteria: Bacteria that stain deep purple in response to Gram staining because these cells do not have an outer membrane

Gram-negative Bacteria: Bacteria that stain pink in response to Gram staining because these cells have an outer membrane preventing stain penetration

HAP: Hospital-acquired pneumonia

High-Throughput Screening (HTS): The process of using automated assays to search through large numbers of substances for desired activity, resulting in less costly and faster systematic processes

Hit: A “hit” indicates that a compound has interacted with a target to produce a desired effect

Immunoglobulin: A general term for the kind of globular blood proteins that constitute antibodies. A tetrameric protein composed of two identical light chains and two identical heavy chains. Specific proteins produced by derivatives of B lymphocytes that interact with and help protect an organism from specific antigens

In-patient: A patient whose care requires a stay in a hospital

In vitro: Outside a living organism (e.g. in test tubes)

In vivo: Within a living organism

IND: Investigational New Drug Application; the application submitted to the FDA requesting permission to initiate human clinical trials

Lead: A more advanced “hit” and indicates that the chemical structures of the compounds are known (there is a structure)

Lead Compound: A distinct chemical structure that has shown promising biological activity in assays

Lipopeptide: A compound of amino and fatty acids

Metastatic Infection: Spread of infection from the original source to other parts of the body; most commonly infections are spread by the bloodstream

MIC: Minimum Inhibitory Concentration; the minimum concentration of antibiotic necessary to achieve stasis

MIC50: minimum inhibitory concentration of 50% of strains of a specific organism

MIC90: minimum inhibitory concentration of 90% of strains of a specific organism

Microbe: A minute living organism capable of causing disease

Modified Duke Criteria: A validated set of criteria developed at Duke University that can be used by physicians to assess the likelihood that a patient has endocarditis using blood culture results, vital signs, risk factors, clinical findings and the results of heart imaging studies

Monoclonal Antibody: An antibody that is produced artificially from a single cell clone and therefore consists of a single type of immunoglobulin

MRSA: Methicillin-Resistant *Staphylococcus aureus*

MSSA: Methicillin-Susceptible *Staphylococcus aureus*

Natural Product: Any product found in nature

NDA: New Drug Application filed with the FDA, once clinical trials have concluded and data analyzed, requesting marketing approval

Nosocomial: Acquired in the hospital

Non-inferiority: A statistical trial design commonly used in the pharmaceutical industry to demonstrate that a new drug is not statistically inferior in effectiveness than a currently approved drug, within parameters established in the design

Osteomyelitis: Refers to a bone infection, almost always caused by a bacteria. Over time, the result can be destruction of the bone itself (also Osteo)

Out-patient: A patient who is not an in-patient (not hospitalized) but instead is cared for elsewhere -- as in a doctor's office, clinic, or day surgery center

Pathogen: A disease-causing organism

Penicillin: An antibiotic substance extracted from cultures of certain molds

Peptide: A short chain of amino acids

Pharmacoeconomics: The simultaneous comparison of a drug against one or more alternate (drug or non-drug) treatments with respect to both costs and outcomes

Pharmacokinetics: The process by which a drug is absorbed, distributed, metabolized, and eliminated by the body (also the study of this process)

Pharmacovigilance: The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem (also the same as ‘drug monitoring’)

Pre-clinical: A study to test a drug, procedure or medical treatment in animals (to collect data in support of safety) Preclinical studies are required before clinical trials can be started

Prokaryotic Cells: Cells that lack a membrane-bound nucleus

Proteins: Large molecules composed of amino acids that control most biological reactions in the body and receive and transmit most of the chemical signals within and between cells

SAE: Serious adverse event

Safety: The condition (or state of) being safe; free from danger, hazard, exemption from hurt, injury, or loss

Scaling: The process of taking a microbe which secretes an antibiotic in a 20 microliter volume, and reproducing the output in a big volume

sNDA: Supplemental New Drug Application

Staphylococcus aureus: A pathogen that causes a variety of diseases (or *S. aureus*)

Susceptible: Likely to be affected

Toxicity Studies: The study of degree to which a substance can harm humans or animals (also “Tox” studies)

VAP: Ventilator-Associated Pneumonia

VISA: Vancomycin Intermediate-Resistant *Staphylococcus aureus*

VRE: Vancomycin-Resistant Enterococci

VRSA: Vancomycin-Resistant *Staphylococcus aureus*

WAC: Wholesale acquisition cost