

BIOMEA FUSION

MASTER GLOSSARY

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INTRODUCTION

The definitions as provided here are not meant to include all possible definitions but only those that are typically applicable within the field of Biomea Fusion' activities. The definitions can only provide a first understanding of technical terms, further study may be required.

The definitions provided here are not intended to diagnose or offer medical advice.

Biomea Fusion Commonly Encountered Abbreviations, Acronyms & Symbols

AACR	American Association of Cancer Research
ADR	Adverse Drug Reaction
AE	Adverse Event
A1C	Hemoglobin A1c
API	Active Pharmaceutical Ingredient
ASCO	American Society of Clinical Oncology
ASH	American Society of Hematology
ALL	Acute Lymphocytic Leukemia
AML	Acute Myeloid Leukemia
AUC	Area Under The Curve
CME	Continued Medical Education
CLL	Chronic Lymphocytic Leukemia
CR	Complete Response
DNA	Deoxyribonucleic Acid
Dx	Diagnosis
DLBCL	Diffuse Large B-cell Lymphoma
ECOG	Eastern Cooperative Oncology Group
FDA	Food & Drug Administration
FPI	First Patient In
HCP	Health Care Professional
IRB	Independent Review Board
IV	Intravenous
IC	Inhibitory Concentration
KOL	Key Opinion Leader
MAD	Multiple Ascending Dose
MM	Multiple Myeloma
MLL	Mixed Lineage Leukemia
MM	Micro Molar
ML	Milliliter
NCI	National Cancer Institute
Ng	Nanogram
NCE	New Chemical Entity
NDA	New Drug Application
NHL	Non-Hodgkin's Lymphoma
NM	Nano Molar

NME	New Molecular Entity
NP	Nurse Practitioner
ONC	Oncologist
PD	Pharmacodynamics
PK	Pharmacokinetics
POS	Probability of Success
QD	Once Daily
R&D	Research & Development
RNA	Ribonucleic Acid
SAD	Single Ascending Dose
SCT	Stem Cell Transplant
SEER	Surveillance, Epidemiology, and End Results Program
STZ	Streptozotocin-Induced Diabetes (STZ) Model
TPP	Target Product Profile
Tx	Treatment
ZDF	Zucker Diabetic Fatty Rat Model

BIOMEA FUSION GLOSSARY MAIN ENTRY WORDS

A

AACR: American Association of Cancer Research, a global organization of cancer researchers.

Acute: Short duration or immediate. May also indicate severe disease or need for immediate medical intervention.

Acute Infections: An infection that develops rapidly and only lasts a short time.

Acute Myeloid Leukemia: AML is the most common form of acute leukemia in adults and is responsible for the largest number of annual leukemia deaths in the U.S. and Europe. AML originates within the white blood cells in the bone marrow and can rapidly move to the blood and other parts of the body, including the lymph nodes, spleen, and central nervous system. Approximately 20,000 people in the U.S. are diagnosed with AML each year, and the five-year overall survival rate in adults is roughly 29% (Source: NCI SEER Data).

Acute Lymphocytic Leukemia: ALL is a less common leukemia, with approximately 6,000 new cases in the U.S. each year and a higher five-year survival rate of nearly 70% (Source: NCI SEER Data). Unlike AML, ALL is the most common leukemia in kids and occurs when the blood marrow makes too many lymphocytes a types of white blood cell.

Affinity: An attraction or force between particles that causes them to interact. More specifically, Affinity is a measure of the binding force, or strength, of a single site where an antibody and antigen combine.

Amino Acids: Molecules that are the building blocks of proteins. These molecules have distinct structures and are assembled into proteins based on instructions included in genetic material.

A1C: HbA1C or A1C is a biomarker used to determine how much glucose was in the blood stream in the recent past (usually 3 months). Diabetics use this metric to determine if they have controlled or uncontrolled disease.

Apoptosis: Programmed cell death, a process where the cell begins a series of actions that lead to its controlled death.

ASH: American Society of Hematology, a professional organization that studies blood related disorders.

AUC: Area under the curve is used in the calculation of the amount of drug that was present in the body over a given time. It is usually used in the context of the pharmacokinetics of a drug.

B

Baseline: Refers to information from the beginning or pre-treatment portion of a study. This is used to evaluate the relative changes that occur during the course of the study or therapy.

Baseline ECOG Performance Status: The fitness of a patient for treatment at the beginning of the treatment (baseline), as assessed by a scale developed by ECOG, which evaluates a patient's ability to tolerate / respond to certain types of cancer treatment (e.g. chemotherapy).

B-cell: A type of white blood cell that is part of the adaptive immune system. B-cells can recognize antigens (e.g. viruses, bacteria, chemicals, or pollen) and develop into plasma cells, which produce antibodies that help facilitate immunity. These cells can also turn into antigen presenting cells, which help activate other cells during an immune reaction and also secrete molecules called cytokines that facilitate communication between cells. Eventually, some B cells mature into bone marrow cells.

B-cell Lymphoma: Type of Non-Hodgkin's lymphoma (NHL), representing nearly 85% of NHL. B-cell lymphomas are cancers of the B-cell that include the following lymphomas: Diffuse large B-cell lymphoma (DLBCL), Follicular lymphoma, Chronic lymphocytic leukemia (CLL) /small lymphocytic lymphoma (SLL), Mantle cell lymphoma (MCL), Burkitt lymphoma, Waldenstrom macroglobulinemia, Hairy cell leukemia, Primary central nervous system (CNS) lymphoma, and Primary intraocular lymphoma.

Beta Cells: Pancreatic cells that sense glucose and produce insulin.

Bioavailability: The portion of a dose of drug that is absorbed and reaches the systemic circulation.

Biogenesis: The creation of substances by living organisms.

Biomarker: (Short for biological marker) Anything that can be used as an indicator of the physiological state of an organism and any function or process within it.

Blood: A bodily fluid that distributes nutrients and oxygen to the various cells/tissues of the body and transports waste products away from those same cells/tissues. It contains blood cells and plasma, a liquid that makes up more than half of the volume of blood.

Blood Cell: These cells are mostly found in blood. The key types of blood cells include red blood cells that primarily transmit oxygen, white blood cells (leukocytes) that are part of the immune system that protect the body from infectious disease among other things, and platelets.

BMF-219: an irreversible covalent menin inhibitor invented by Biomea Fusion.

Bone marrow: Tissue in the hollow central cavity of bones where blood cells are produced.

C

Cancer: A term used for diseases where cells that have accumulated genetic mutations that enable them to divide without control and sometimes spread throughout the body. As cells divide without control, they may form a mass, which is called a tumor. Tumors can be cancerous or benign (meaning that they are not cancerous). Cancers can be defined by the region of the body in which they start (primary site) and/or by the type of tissue (histology) where they begin.

Cell: A basic unit of a living organism. Cells are the building block of tissue as one brick is part of a brick wall. There are also cells with specialized functions in various places in the body, such as the blood and other fluids.

Cell Proliferation: An increase in the number of cells as a result of cell growth and cell division.

Chemotherapy: Common in cancer treatment, chemotherapy is the treatment of diseases via cytotoxic drugs with the purpose of killing fast-growing cells.

Chromosome: A structure within the body that contains genetic material (DNA) and proteins. DNA is tightly packed in these structures in order to maintain its integrity. In cancer, chromosomes can break and reattach in the wrong place, producing a chromosomal translocation. These can lead to fusion proteins that can lead to cancer / accumulate in cancer cells.

Clinical Trial/Clinical Study: A research study that typically assesses the performance of a treatment in human subjects. These studies are governed by a specific set of ethical rules and regulations to ensure that safety of patients.

Covalent Bond: A covalent bond is the interaction between two atoms that involves the sharing of electron pairs. It is used to also describe the type of bond a medicine can have with its target in the human body.

CR (Complete Response/Remission): The total disappearance of the cancer based on various tests conducted by a physician.

CYP: Mainly found in the liver and also the small intestine, these metabolic enzymes are known as the cytochrome P450 superfamily of enzymes (officially abbreviated as CYP). Six of these enzymes metabolize 90 percent of drugs. Notably, the two most significant enzymes are CYP3A4 and CYP2D6.

CYP Inhibitors: A substance that slows or stops the activity of the enzymes in the CYP family.

CYP Substrates: A molecule that is broken down/metabolized by a CYP enzyme.

Cysteine Residue: Cysteine is an amino acid that allows BMF-219 to bind to and inhibit the menin-MLL interaction. Residue, in this case, means a recognizable part of a larger molecule. Amino acids are essential building blocks of proteins, and as such can be referred to as residues of the larger protein chain.

Cytotoxic: Toxic to living cells, cell-toxic, cell-killing. Indicates that the substance or agent will result in cell killing at some concentration.

D

Diabetes Mellitus: A condition characterized by hyperglycemia (high blood glucose) resulting from the body's inability to use blood glucose for energy. In Type 1 diabetes is mediated by autoimmune dysfunction, the pancreas no longer makes insulin and therefore blood glucose cannot enter the cells to be used for energy. In Type 2 diabetes, either the pancreas does not make enough insulin, or the body is unable to use insulin correctly.

Differentiation: A process where less specialized cells mature into a different cell type. It is a natural process in the development of some cells. This occurs with leukemic cells following exposure to certain treatments. These treatments try to induce differentiation to reduce the number of leukemic cells.

Diffuse Large B-Cell Lymphoma: Diffuse large B-cell lymphoma (DLBCL) is the most common type of non-Hodgkin lymphoma. It is a fast-growing (high-grade) lymphoma. It develops from abnormal B cells that are larger than normal B cells. When assessed under a microscope, these abnormal cells appear spread out (diffuse) rather than grouped together.

Deoxyribonucleic Acid (DNA): Double stranded nucleic acid that contains critical genetic information. DNA is stored in the nucleus and is typically tightly packed (coiled) in order to preserve its integrity and not lose any genetic information. There is an involved process to uncoil portions of DNA to help make proteins and carry out other functions.

E

Eastern Cooperative Oncology Group (ECOG): A large network of medical institutions, which work toward curing cancer. This group is associated with ECOG performance status, a grading system that is used to assess the fitness of patients for various cancer treatments.

Electron: A very small particle of matter that has a negative charge, the basic charge of electricity, and travels around the nucleus of an atom. Covalent bonds between two molecules involve the sharing of electrons.

Encode: Typically refers to a gene specifying the instructions (code) for making a protein

Epigenetics: Epigenetics is the study of how cells control gene activity without changing the DNA sequence. "Epi-" means on or above in Greek, and "epigenetic" describes factors beyond the genetic code. Epigenetic changes are modifications to DNA that regulate whether genes are turned on or off.

Exposure: The amount of drug in the body following administration.

Ex-Vivo: Refers to tissue taken from an organism, typically for the purpose of scientific experimentation.

F

Fusion Protein: Proteins created through the joining of two or more genes (typically via a process called translocation) that were originally not close enough to allow for them to produce a protein together. The resulting Fusion Protein has functional properties derived from each of the original proteins. These proteins can have an outsized role in oncogenesis in a variety of cancer types and are therefore interesting targets for pharmacological intervention.

G

Gene: Basic unit of heredity, comprised of a sequence of nucleotides (sub-components of nucleic acid). Genes may encode gene products, RNA, or protein.

Grades/ECOG Performance: Eastern Cooperative Oncology Group (ECOG) has established a scale that evaluates a patient's ability to tolerate / respond to certain types of cancer treatment (e.g. chemotherapy). It is occasionally referred to as a patient's biological age. The ECOG grade are included below:

Grade 0: Fully active, able to carry on all pre-disease performance without restriction

Grade 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work

Grade 2: Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours

Grade 3: Capable of only limited self-care, confined to bed or chair more than 50% of waking hours

Grade 4: Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

Grade 5: Dead

Grade for Adverse Event: Adverse events are any untoward medical occurrence in a clinical trial setting. Importantly, these events may not necessarily be caused by the treatment in the clinical trial. Grade refers to the severity of the adverse event (AE) as follows:

Grade 1: Mild AE

Grade 2: Moderate AE

Grade 3: Severe AE

Grade 4: Life-threatening or disabling AE

Grade 5: Death related to AE

H

Half-Life: The time for a drug to drop to half of its concentration in blood.

Hematological: Related to blood or the study of blood, blood-forming organs, and blood diseases.

Hodgkin's Lymphoma: One of the two types of Lymphoma, which is a type of cancer that primarily impact the lymphatic system. These cancers are dividing into Hodgkin's and non-Hodgkin's lymphoma based on whether a specific type of cell, called Reed-Sternberg cells, are present. These cells are present in Hodgkin's lymphoma and are not present in non-Hodgkin's lymphoma. Hodgkin's lymphoma is less common than non-Hodgkin's lymphoma.



Indication: The specific approved use of a medicinal product received from a regulatory agency, such as the FDA.

Inhibitor: A substance that slows or halts a physiological process.

Insulin: A key protein that facilitates that cellular processing of glucose, a key source of energy for cells. This protein, also referred to as a hormone, is critical for the diabetes disease process as it is not produced in sufficient quantified and/or the body can no longer properly use insulin

In Vitro: Outside of the body, in a test tube, or sample/culture of some sort.

In Vivo: Within the body of a human or animal. **Vivo:** Latin for “live”.

K

L

L: Liters, a metric unit of capacity, formerly defined as the volume of 1 kilogram of water under standard conditions, now equal to 1,000 cubic centimeters.

Leukemia: Also referred to as liquid or blood cancers, Leukemias are cancers of the bone marrow and are typically characterized by the overproduction of white blood cells. Notable leukemias include AML and ALL.

Leukocytes: White (colorless) blood cells that defend the body against disease and infection.

Ligand: A substance that forms a complex with a biological molecule for a biological purpose.

Ligand Efficiency: A value that is a function of a ligand's binding energy versus its weight. This is a key property for small molecule development.

Lymphoma: Lymphoma is cancer of the lymphatic system, which helps purify/filter bodily fluids in addition to producing special white blood cells that fight infection. These cancers are dividing into Hodgkin's and non-Hodgkin's lymphoma based on whether a specific type of cell, called Reed-Sternberg cells, are present. These cells are present in Hodgkin's lymphoma and are not present in non-Hodgkin's lymphoma.

M

Mechanism of Action (MOA): The biochemical process of how a drug works in a biological system and the effect the drug has on a living organism.

Medium CYP Inhibitor: A substance that slows or stops the activity of the enzymes in the CYP family to a moderate extent.

Menin: Menin is a protein important to transcriptional regulation, impacting major processes such as cell cycle control, apoptosis, and DNA damage repair. It plays an essential role in oncogenic signaling in subgroups of genetically defined leukemias, such as mixed lineage leukemia – rearranged (MLL-r) and other cancers dependent on menin. It can be described as a scaffold protein

Metabolism: The chemical processes within a cell for the purpose of life.

Micromolar (μM): A micromole is a unit of measurement that is 1,000 times smaller than a millimole.

Milliliter (ml): Also referred to as a cubic centimeter (cc), mL is a unit of volume equal to one thousandth of a liter

Mixed Lineage Leukemia (MLL): This gene also known as KMT2A, which codes for a gene regulator called a histone methyltransferase. This enzyme helps to turn on and turn off gene expression.

Mixed Lineage Leukemia-rearrangement (MLL-r): MLL-r leukemias are characterized by translocation abnormalities to the MLL gene (also known as KMT2A).

Mole: A chemical mass unit, defined to be 6.022×10^{23} molecules, atoms, or some other unit.

Molecular Weight: Used for assessing the size of a molecule, molecule weight is the sum of the atomic weights (also known as atomic mass) of all the atoms in a molecule.

Molecule: A grouping of atoms held together by chemical forces.

Multiple Myeloma: Multiple myeloma is a cancer that forms in a type of white blood cell called a plasma cell. Healthy plasma cells fight infections by making antibodies that recognize and attack pathogens. In multiple myeloma, cancerous plasma cells accumulate in the bone marrow and crowd out healthy blood cells. Rather than produce helpful antibodies, the cancer cells produce abnormal proteins that can cause complications.

Mutation: A change in the DNA of a cell or an organism, typically in the context of a specific gene or set of genes. Mutations fall into specific categories based on where they occur in relation to the gene of interest.

MYC: A family of transcription factors (c-myc (MYC); l-myc (MYCL); and n-myc (MYCN)) that regulate growth and cell cycle (the process a cell uses to grow and divide) entry. Particularly relevant in for growth and cell entry in cancer

Myeloid: Of or relating to bone marrow.

Myeloma: A cancer that begin in the cells of the immune system.

N

N or n: In statistics N refers to population size; and n, to sample size.

National Cancer Institute: An institute that the federal government uses to support cancer training and research.

Ng · hr/mL: nanogram times hour per milliliter. Used for precise monitoring of very small levels of a drug in the body.

Ng/mL: Nanograms per milliliter.

Nm: A nanomole is a unit of measurement that is 1,000 times less than a micromole. These measurements usually correspond to drug concentration in the body

Nonclinical: A refers to a series of actions / experiments that occur before clinical trials (testing in human subjects) can begin.

Nonclinical Toxicology: The process of assessing the safety profile in animals, typically required prior to administering a new drug into human subjects in a clinical trial.

Non-Hodgkin's Lymphoma (NHL): All kinds of lymphomas except Hodgkin's disease, which is a malignant (cancerous) form of lymphoma marked by progressive enlargement of the lymph nodes and spleen and sometimes of the liver

NPM1: also known as nucleolar phosphoprotein B23 or numatrin, NPM1 is associated with nucleolar ribonucleoprotein structures and binds single-stranded and double-stranded nucleic acids (RNA and DNA). It is involved in the biogenesis of ribosomes and may assist small basic proteins in their transport to the center of the nucleus, called the nucleolus.

Nucleus: A sub-compartment of the cell where genetic material (DNA) is stored.

Nucleic Acid: A complex organic substance present in living cells, especially such as DNA (Deoxyribonucleic Acid) which is a molecule that encodes the genetic instructions (blueprint) used in the development and functioning of all known living organisms.

O

Oncology: A medical specialty focused on the diagnosis and treatment of cancer, including medical oncology, radiation oncology, and surgical oncology.

Oncogenesis: The biological steps leading to the development of a cancer cell.

Oral Administration: Dosing of a medication by mouth.

P

P (as in $p < 0.0001$, $p < 0.05$): The letter "p" refers to p-value, or the chance that something will happen by chance. The lower the p-value, the less likely the result of an experiment is due to chance.

Pancreas: An organ located in the back of the abdomen, behind the liver and stomach. The pancreas makes hormones, including insulin.

Pathway: A biological process related to specific actions with molecules in a cell that results in specific product or outcome.

Pediatric: Pertaining to the health of children.

Pharmacodynamics (PD): The study of how a drug impacts the body, typically via a therapeutic action. This data is used to determine the appropriate dose of the drug.

Pharmacokinetics (PK): The study of how the body processes a drug. Much of this is related to metabolism, how the body excretes or gets rid of the drug.

Pharmacology: Refers to the study of uses, effects, and actions of drugs or the characteristics or properties of a specific drug.

Phase 1 Study: Phase 1 includes the initial introduction of an investigational new drug into humans.

Phase 2 Study: Phase 2 includes the early controlled clinical studies, typically following Phase 1, conducted to obtain some preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition.

Phase 3 Study: Phase 3 studies are expanded controlled and uncontrolled trials. These studies assess the safety and effectiveness of the drug.

PK Data (Pharmacokinetic Data): This data helps determine how the body metabolizes the drug, how it excretes or gets rid of the drug and what the side effects might be at different doses.

Plasma: The clear, protein-rich fluid which is left behind when the blood cells are removed from the blood.

Plasma Concentrations: The amount of drug in your blood.

Platelets: Platelets are a component of blood that typically aids the clotting process

PR (Partial Response): The condition in which the decrease in the tumor is at least 50% but less than 100%.

Primary Endpoint: The main objective of a clinical study.

Progression: In the context of disease progression, in relation to cancer, when it continues to grow, spread, or become more severe.

Protein: Proteins are sequences of amino acids which are molecules that are linked together in

various combinations to make up the long molecular chains that are proteins. Proteins perform key functions in a multitude of different ways.

R

Randomized: Selected at random for some purpose.

Randomized Clinical Trial: A study in which the participants are assigned by chance to separate groups that compare different treatments.

Range: The area of variation between upper and lower limits on a particular scale.

RAS/RAF: Refers to specific molecules involved in the RAS (Rat sarcoma virus GTPase) / RAF (Rapidly accelerated fibrosarcoma kinase) / MEK (Mitogen activated protein kinase) / ERK (Extracellular signal related kinases) signaling pathway, which occasionally goes awry in cancer cells.

Rearranged: refers to cancers that have undergone a translocation resulting in a fusion protein, which is relevant to the oncogenic processes associated with the development of that cancer type.

Regimen: A treatment plan that specifies the dosage, the schedule, and the duration of treatment.

Remission: Disappearance of signs and symptoms of disease. A remission is a temporary end to the medical signs and symptoms of a disease that has not been cured.

Response rate: The percentage of patients whose cancer shrinks or disappears after treatment.

Reversible Binding: A reversible interaction (kinetics) of various drugs with body components such as proteins.

Ribosomes: Ribosomes perform the function of protein synthesis, translating a sequence of RNA into proteins. Ribosomes are cellular components that are essential for function of the cell.

RNA: Ribonucleic acid, which is a single stranded nucleic acid, is an intermediate carrier of genetic information that helps to transcribe the DNA into proteins.

S

Scaffold Protein: A protein that supports other proteins in a complex.

SEER: The surveillance, epidemiology, and end results (SEER) program at the national cancer institute works to collect and analyze data about the number of cancer cases and deaths in the United States.

Side Effects: Any unwanted nontherapeutic effect caused by a drug.

Single Agent: A trial where only one drug is used versus trials with several drugs in combination.

Single Dose AUC Values: Refers the amount of drug the body is exposed to from a single dose. AUC is an abbreviation for Area Under the Curve; reflects the amount of drug the body is exposed to; depends on the dose of medication given and how fast it is metabolized and cleared from the body.

Small-Molecule: A molecule with a low molecular weight.

Standard Deviation: A statistical measure of the amount that a set of values differs from the average.

Statistically Significant: When a statistic is significant, it means that the result of an experiment is unlikely to be due to chance based on the constraints set by the experimenter.

Stem Cell: Stem cells are the immature cells that are created in the bone marrow and can develop into various specific cells in the blood.

Stem Cell Transplant: The transplantation of healthy stem cells into the body, typically used as a cancer treatment.

Streptozotocin-Induced Diabetes (STZ): A preclinical model of diabetes where diabetic features are induced via a toxin that selectively kills pancreatic beta cells, which are key producers of insulin. This model produces disease features that can be associated with either type 2 or type 1 diabetes.

Strong CYP Inhibitor: A substance that slows or stops the activity of the enzymes in the CYP family to a great extent. These enzymes are known as the cytochrome P450 superfamily of enzymes (officially abbreviated as CYP).

Survival: Staying alive, continuation in life or existence.

Systemic: Throughout or considering the entire body.

T

Target: A thing in a cell to which something binds to or is directed towards. On-Target effects indicate that the effect is the result of a direct interaction with the intended target.

Therapeutic Window: The range of the amount of a therapeutic agent or drug that causes the therapeutic effect to the amount that causes death (in animal studies) or toxicity (in human studies). Drugs with a large therapeutic window have the potential to provide an efficacious dose without being toxic.

Tissue: A part of the body of a living thing that is made of similar cells.

Toxicity: Having to do with poison or something harmful to the body.

Toxicology: The study of the nature, effects, and detection of poisons and the treatment of poisoning.

Translocation: A phenomenon that results in unusual rearrangement of chromosomes via specific and well-elucidated processes.

Transcription Factor: A protein that is involved in the production of RNA from DNA, typically controlling how much RNA is made from a portion of DNA.

Tumor: A swelling of a part of the body, generally without inflammation, caused by an abnormal growth of tissue.

U

Unit: A quantity chosen as a standard in terms of which other quantities may be expressed.

V

Value: A numerical quantity that is assigned or is determined by calculation or measurement.

W

X

Xenograft: Tissue or an organ that of or derived from a species other than what it is implanted in. Xenografts are frequently used as part of preclinical animal models to study the effects on drugs specific tumors in an animal.

Y

Z

Zucker Diabetic Fatty Rat: A rat based preclinical model of diabetes where the disease features are induced via a high fat diet. This model creates disease features that are mainly associated with type 2 diabetes.