Cellular & Noncellular Therapies Naming Scheme

Introduction

The nomenclature scheme for cellular and noncellular therapeutic products, described in this report, was developed by the USAN working group for cell therapies. Under the scheme, the cell type/source and product manipulation or modification would be part of the cellular therapy product name, incorporated as infixes (Appendix 1). The suffix -cel would be used for all cell therapies, and -imut for noncellular immunotherapeutic products. The USAN Council would review the prefixes suggested by the manufacturer for each name; the prefix would provide uniqueness for products in the same category.

Scope

This naming scheme would apply to all cell therapy products, with the exception of minimally manipulated hematopoietic elements, combination products and prophylactic vaccines. The scheme also covers nonrecombinant peptide and protein preparations from cells/tissues used in immunotherapy; however, it does not apply to chemically synthesized peptides or recombinant proteins. Since most cell therapy products are manipulated or modified in some way, the manipulation or modification would be considered as part of the product and would hence be part of the name. Such manipulation/modification would include transduction of cells with vectors or viruses, fusion of cells with tumor cell lines, or pulsing of cells with peptides, cell lysates or other agents.

Please note: The following are not covered by the Cell and Gene therapies scheme: minimally manipulated hematopoietic elements including minimally manipulated umbilical cord blood and peripheral blood stem cells for transplant; combination products, which include combinations of cells with non-cellular pharmaceutical products (cell/device, cell/drug combination products); prophylactic vaccines; tissue engineered products; induced pluripotent stem (iPS) cells; embryonic-derived cell therapies; and veterinary cellular therapies.

Cellular Therapy Naming Scheme

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Specification of name elements:

**Prefix:** Suggested by manufacturer and reviewed by USAN Council (to provide uniqueness)

**Infixes:** May include

- manipulation (-fus = fused with peptide, cells or other agent)
- cell type (e.g., -myo = myoblast, -isla (formerly known as -isle) = islet cell, -den = dendritic cell)

**Suffixes:** -cel (stem for cell therapies) is used for all cell therapies

**Product name composition:** Prefix + Infix 1 + Infix 2

Infix 1 = Manipulation (there may be more than one infix)

Infix 2 = Cell Type/Source

There may be more than 1 infix in the name.

**Guidelines for Naming Cell Therapies:**

The primary cell type in the product will always precede the stem -cel. Residual or contaminating cells would not be part of the name. Information on contaminating cells and reagents would be included in the package insert. Example: an autologous fibroblast cell product is -fibrocel or -ficel.

1. Infixes for manipulation would always precede the infix for the cell type/category.
2. If a product manipulation such as fusion to a tumor cell has occurred, the infix -fus (for fusion) would be part of the name. A description of the article(s) that have been fused to the primary cell will be provided in the package insert. For example, a dendritic cell product that has been fused with various tumor cells would be -fusdencel.
3. If the primary cells have been transduced with a vector/virus, the infix -gen- is used. Example: Plasmid DNA transduced retinal epithelial cells, -genretcel.
4. To distinguish between the various stem cell types, the infix for the cell type would precede the infix for progenitor -tem. For example, a neuronal stem cell will be designated as -neurotemcel.
5. For tumor/cancer cell lines used in preparing therapeutic immunomodulators (cancer vaccines), the infix for the tumor cell type/source is not included. These products are cellular products.
6. Prophylactic vaccines are given descriptive names (e.g., hepatitis B vaccine). This is in contrast to therapeutic immunomodulators, which are frequently referred to as cancer vaccines. Therapeutic immunomodulators prepared using noncellular agents such as nonrecombinant

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proteins and peptides isolated from cells/tissues or cell lysates should have suffixes that set them apart from cellular immune modulators (cellular cancer or tumor vaccines). The suffix -imut (immunotherapeutics) is proposed. The infixes -lis (cell lysate), -pep (peptide), -pro(t) (protein) would precede the stem -imut to generate the sub-stems for the various noncellular vaccines: -lisimut (cell lysates), -pepimut (peptide), and -protimut (protein).

7. The term immune cell or leukocyte (infix -leu-) will be used to describe hematopoietic cell preparations that do not fit a particular or specific cell type. Such cell preparations may be comprised of a mixture of the various blood cell elements, a subset of blood elements such as T-B- or NK-cells, or antigen presenting cells (APCs) that do not fit the definition of dendritic cells fall into this category.

8. A product manipulation such as activation (with cytokines/drug, etc.) will not be part of the name.

9. Details of the manipulations and/or modifications would be described in the package insert.

10. The USAN Council would review the prefixes suggested by the manufacturer for each name to provide uniqueness for the names.

Appendix 1 - Proposed Infixes for Cellular Therapy Products

Infixes for Products

dendritic cell: -den
islets: -isle
myoblast: -myo(b)
chondrocytes: -cho(n)
fibroblasts: -fi(b)
keratinocytes: -ker(a)
endothelial cells: -end(o)
hepatocytes: -hep(a)
mesenchymal stromal cells (msc): -mestro-
retinal epithelial cells: -ret

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renal tubular cells: -ren
placenta cells: -pla(c)
urothelial cells: -ur
tumor cells:
  -tucel-
gonad cells:
  ovary: -ova-
  testis: -tesi-
peripheral blood:
  primary cord blood: -cor
  lymphocytes/monocytes/APC: -leu- (white cells)
stem cells:
  -tem-
  neuronal: -neurotem-
  bone marrow: -myelotem-

**Infixes for Manipulation**

fused: -fus

**Noncellular Therapy Naming Scheme**

**Suffixes**
-imut (stem for therapeutic immunomodulators) is used for all noncellular therapy products, which include cell lysates, recombinant peptides or proteins (isolated from cells/tissues) used for cancer vaccines. Sub-stems for these vaccines are as follows:

-lisimut (stem for cell lysates)
-pepimut (stem for peptides)
-protimut (stem for protein)

Heat shock: -tespen-

**Qualifiers:** Letter after hyphen at end of name

R = Recombinant
S = Synthetic
T = Autologous