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New INN monoclonal antibody (mAb) nomenclature scheme

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Suffixes/stems

As the previous INN nomenclature scheme for monoclonal antibodies (mAb), this new INN mAb nomenclature scheme is used for all substances that contain an immunoglobulin variable domain that binds to a defined target, and that is composed of only immunoglobulin-derived pharmacologically active components. The suffix is preceded by an infix that indicates the target class.

However, in contrast to the previous INN mAb nomenclature scheme, the new INN mAb nomenclature scheme divides the substances that contain an immunoglobulin variable domain into four groups, there being three groups for monospecific immunoglobulins and one for bi- and multi-specific immunoglobulins, independent of their type, shape and form.

Group 1 **-*tug* for *unmodified immunoglobulins***   Monospecific full length and Fc unmodified[1] immunoglobulins of any class. Molecules which might occur as such in the immune system. Including: - IgG, IgA, IgM, IgD, IgE   - only allelic variants   - Glycoengineering without mutation   - C-terminal lysine deletion without any other mutation in the Fc region
Group 2 **-*bart* for *antibody artificial***   Monospecific full length immunoglobulins with engineered constant domains (CH1/2/3).   Monospecific full length immunoglobulins that contain any point mutation introduced by engineering for any reason anywhere (hinge, new glycan attachment site, mixed allelic variants which would not occur in nature, altered complement binding, altered FcRn binding, altered Fc-gamma receptor binding, etc.)   *e.g*. IGHG4 with S>P mutation, stabilized IgA
Group 3 **-*mig* for *multi-immunoglobulin***   Bi- and multi-specific immunoglobulins regardless of the format, type or shape (full length, full length plus, fragments)
Group 4 **-*ment* for *fragment***   All monospecific domains, fragments of any kind, derived from an immunoglobulin variable domain (all monospecific constructs that do not contain an Fc domain)

[1] Do not contain any amino acid differences with the native sequence (constant region amino acid changes by comparison with the closest genomic C gene and allele).

Note1: Immunoglobulin fusions are only included in the monoclonal antibody nomenclature scheme if both domains have immunoglobulin derived variable domains (*eg*. mAb fused with a cytokine is under the *-fusp* nomenclature scheme).

Note2: Antibody-drug conjugates (ADC) also follow this new mAb nomenclature scheme and no special suffix is added, as the second word indicates that the substance is a conjugate.

Infixes

The mechanisms of monoclonal antibodies are complex, may be different for different indications may and might not be completely understood during development. Therefore, the infix is assigned according to the proposed known mode of action at the time of the INN request.

The changes for the new scheme are in green.

Infix	Definition
-ami-	serum amyloid protein (SAP)/amyloidosis *(pre-substem)*
-ba-	bacterial
-ci-	cardiovascular
-de-	metabolic or endocrine pathways
-eni-	enzyme inhibition
-fung-	fungal
-gro-	skeletal muscle mass related growth factors and receptors *(pre-substem)*[1]
-ki-	cytokine and cytokine receptor[2]
-ler-	allergen
-sto-	immunostimulatory
-pru-	immunosuppressive
-ne-	neural
-os-	bone
-ta-	tumour
-toxa-	toxin
-vet-	veterinary use *(sub-stem)*
-vi-	viral

[1] At the 69th INN Consultation, the infix changed from *-gros-* to *-gro-* to avoid a conflict with the infix *-os-*.