EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 January 2017
EMA/54559/2017
Inspections Human Medicines Pharmacovigilance Division
Committees and Inspections Department

Scientific recommendation on classification of advanced therapy medicinal products

Article 17 – Regulation (EC) No 1394/2007

Disclaimer: This document is a summary for public release of a scientific recommendation on classification of advanced therapy medicinal products. The original text adopted by the Committee for Advanced Therapies (CAT) has been redacted to delete commercially confidential information.

The present scientific recommendation refers exclusively to the case as presented to the European Medicines Agency (EMA) without prejudice to future evaluations by the Agency.

It is stressed that the scientific recommendation on advanced therapy classification does not amount to any endorsement of the plausibility of the product, including the mode of action or therapeutic indication(s) claimed by the applicant.

Brief description (or name when available) of the active substance(s)

Bone Marrow derived lineage negative heterogenic stem and progenitor cells.

Brief description of the finished product

Autologous lineage-negative heterogenic stem/progenitor cells isolated from bone marrow, prepared as a cell suspension in sterile solution.

Proposed indication

Amyotrophic lateral sclerosis in adults.

EMA/CAT conclusion

The procedure was finalised on 19 December 2016 for the following recommendation.

On the basis that the product:

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- consists of non-substantially manipulated fraction of bone marrow;
- is used on the basis that the product is postulated to secret trophic factors for the regeneration of neurons, which is not the same essential function;
- is presented as having properties for the regeneration and repair of neuron,

the EMA/CAT considers that the Product falls within the definition of a tissue engineered product as provided in Article 2(1) of Regulation (EC) 1394/2007.