EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance & Committees Division

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)

Allogenic bone marrow derived mesenchymal stem cells expanded *in vitro.*

Brief description of the finished product

Mesenchymal stem cells suspended in an injection saline solution in an injection bag.

Proposed indication

Treatment of acute Graft-versus-Host Disease grades III and IV resistant to first line treatment.

EMA/CAT conclusion

The procedure was finalised on 20 May 2016 for the following recommendation.

On the basis that the product:

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- is a biological medicinal product as the human MSC expanded *ex vivo* are extracted from human bone marrow. Characterisation and the determination of its quality require a combination of physico-chemical-biological testing, together with the production process and its control;
- consists of cells that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered (but excluding the manipulations listed in Annex I to Regulation (EC) No 1394/2007);
- is presented as having properties for, or is administered to human beings with a view to treating a disease through the immunological action of its cells,

the EMA/CAT considers that the product falls within the definition of a somatic cell therapy medicinal product, as provided in Article 2(1) of Regulation (EC) 1394/2007.