16 March 2016
EMA/557288/2015
Procedure Management & Committees Support Division
Scientific Committee Support 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

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

Human monocytes-derived suppressive cells, expanded *ex vivo*

Brief description of the finished product

Peripheral blood monocytes-derived suppressive cells, dispersion in human albumin for infusion.

Proposed indication

Treatment of acute Graft-versus-Host Disease refractory to first-line treatment

EMA / CAT conclusion

The committee adopted on 17th July 2015 the following scientific recommendation.

On the basis that:

The product is a biological medicinal product as the human monocytes-derived immunosuppressive cells expanded *ex vivo* are extracted from human peripheral blood. Characterisation and the determination of its quality require a combination of physico-chemical-biological testing, together with the production process and its control.

The product has the following characteristics:

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(a) 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);

(b) 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)(a) of Regulation (EC) No. 1394/2007