12 April 2016
EMA/263760/2016
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)

Hematopoietic progenitor cells, facilitating cells and αβ T cells from mobilized peripheral blood mononuclear cells

Brief description of the finished product

Cell suspension for infusion

Proposed indication

Living Kidney Donor Transplantation

EMA/CAT conclusion

The committee adopted on 16th October 2015 the following scientific recommendation.

On the basis that:

- The product does not consist 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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

- The product consists of cells that are intended to be used for the same essential function in the recipient and the donor

the EMA/CAT considers that the product does not fall within the definition of an advanced therapy medicinal product.