EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 October 2018
EMA/751638/2018
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)

Organ donor derived CD34+ haematopoietic stem cells and a defined dose of donor-derived CD3+ T-cells.

## Brief description of the finished product

Cryopreserved cellular suspension for intravenous infusion.

## Proposed indication

Prevention of graft rejection in recipients of HLA-matched living donor kidney transplant recipients.

## EMA / CAT conclusion

The procedure was finalised on 20 September 2018 for the following recommendation.

On the basis that:

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 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, and;
- 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, as provided in Article 2(1) of Regulation (EC) 1394/2007.