09 September 2018
EMA/608871/2018
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)

Autologous suspension of blood-derived endothelial and hematopoietic stem/progenitor cells.

Brief description of the finished product

Serum-free suspension of endothelial progenitor cells (EPC) and multipotent adult hematopoietic stem/progenitor cells (HSPC).

Proposed indication

Treatment of No-Option Patients with Peripheral Arterial Disease (PAD) and Critical Limb Ischemia (CLI).

EMA / CAT conclusion

The procedure was finalised on 20 July 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 consists of viable 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;
- the product is to be administered to human beings with a view to regenerating, repairing or replacing human tissue,

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.