EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management & Business 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)

Ex-vivo expanded adult human bone-marrow derived pooled allogeneic mesenchymal stromal cells

Brief description of the finished product

Suspension of e*x vivo* expanded adult human bone-marrow derived pooled allogeneic mesenchymal stromal cells

Proposed indication

Thromboangiitis obliterans (Buerger's disease)

EMA/CAT conclusion

On the basis that:

- the product consists of viable human cells that have been subject to substantial manipulation (*ex vivo* expansion) 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),

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- the product is presented as having properties for treating a disease in human beings,

- the product is presented as acting through immunological and trophic mechanism,

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.