EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 bone-marrow derived CD34+ cells.

Brief description of the finished product

Autologous bone-marrow derived CD34+ cell suspension in saline.

Proposed indication

Improvement of neurologic function in patients with non-lacunar acute ischemic stroke infarction.

EMA/CAT conclusion

The procedure was finalised on 20 December 2017 for the following recommendation.

On the basis that the product:

- fulfils the definition of a biological medicinal product;

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

- is used on the basis that the product is postulated to secret trophic factors for the regeneration of neurons, which is not the same essential function;
- is presented as having properties for the regeneration and repair of neural 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.