



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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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)**

Allogeneic ex-vivo expanded placental mesenchymal-like adherent stromal cells

### **Brief description of the finished product**

Cell dispersion for parenteral use

### **Proposed indication**

Treatment of Peripheral Arterial Occlusive Disease (PAOD)

### **EMA/CAT conclusion**

The committee adopted on 17<sup>th</sup> April 2015 the following scientific recommendation.

On the basis that:

- the product consists of viable cells that have been subject to substantial manipulation, so that the 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 treating a disease through the pharmacological action, and also by regenerating or repairing human tissues, via the excretion of various growth or paracrine factors

the EMA/CAT considers that the product falls within the definition of both somatic cell therapy medicinal product and tissue engineered product and based on that is considered as Tissue Engineered Product as provided in Article 2(4) of Regulation (EC) No 1394/2007.