



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

23 April 2019  
EMA/235539/2019  
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)**

*Ex-vivo* expanded allogeneic bone marrow derived mesenchymal stromal cells.

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

Allogeneic bone marrow derived mesenchymal stromal cells suspended in cryopreservation medium.

### **Proposed indication**

Treatment of graft-versus-host disease.

### **EMA/CAT conclusion**

The procedure was finalised on 28 March 2019 for the following recommendation.

On the basis that:

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- the product consists 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;
- the product is administered to human beings with a view to treating a disease through the immunological action of its cells,

the EMA/CAT considers that the product falls within the definition of a somatic cell therapy medicinal product, as provided in Article 2(1) of Regulation (EC) 1394/2007.