



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

21 March 2016  
EMA/213724/2016  
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)**

Autologous cells of stromal vascular fraction of adipose tissue

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

Sterile suspension of autologous cells of stromal vascular fraction of adipose tissue in Lactated Ringers solution

### **Proposed indication**

Treatment of non-healing wounds and scarred tissue

### **EMA/CAT conclusion**

The committee adopted on 25<sup>th</sup> November 2015 the following scientific recommendation.

On the basis that:

- the product is composed of manipulated cells derived from stromal vascular fraction and;
- the product is used for repair of injured tissues in case of non-healing wounds and scarred tissue.

The EMA/CAT considers that the product falls within the definition of a advanced therapy medicinal product (tissue engineered product) for the indication: treatment of non-healing wounds and scarred tissue, as provided in Article 2(1)a of Regulation (EC) No 1394/2007.

