



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Inspections Human Medicines Pharmacovigilance Division  
Committees and Inspections 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.

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 human adipose perivascular stromal cells genetically modified to secrete soluble TRAIL ligand (AD-PC-sTRAIL).

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

Suspension of autologous human adipose perivascular stromal cells genetically modified to secrete soluble TRAIL ligand (AD-PC-sTRAIL) formulated in a saline solution.

### **Proposed indication**

Treatment of TRAIL-sensitive cancers such as Ewing sarcoma and pancreatic ductal adenocarcinoma .

### **EMA/CAT conclusion**

The procedure was finalised on 6 June 2017 for the following recommendation.

On the basis that:



- the product contains an active substance, autologous human adipose perivascular stromal cells genetically modified to secrete soluble TRAIL ligand (AD-PC-sTRAIL), which aims to be administered to human beings with a view to adding a genetic sequence;
- its therapeutic effect relates directly to the product of the genetic expression of soluble TRAIL protein (sTRAIL) in the treatment of TRAIL-sensitive cancers such as Ewing sarcoma and pancreatic ductal adenocarcinoma via an immunological action,

the EMA/CAT considers that the Product falls within the definition of a gene therapy medicinal product as provided in Article 2(5) of Regulation (EC) 1394/2007.