



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

20 December 2013  
EMA/75932/2014  
Procedure Management & Business 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)**

Genetically modified adenovirus coding for human granulocyte-macrophage colony stimulating factor (GM-CSF)

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

Concentrate for solution for injection

### **Proposed indication**

Treatment of cancer

### **EMA/CAT conclusion**

On the basis that:

- The product contains a biological medicinal product as the active substance;
- The active substance is a recombinant nucleic acid 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 this sequence



the EMA/CAT considers that the Product falls within the definition of a gene therapy medicinal product.