



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 February 2014

EMA/113071/2014

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)**

Autologous Lymphoid Effector Cells Specific against Tumour-cells.

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

The product is a suspension of autologous expanded lymphocytes.

It is an autologous immunotherapy product for treatment of cancer produced from the patient's blood. Lymphocytes and monocytes are isolated and using 5-aza-2'-deoxycytidine some cells are induced to express cancer antigens that specifically activate lymphocytes. These activated lymphocytes are expanded and the resulting cell preparation is administered to the patient.

### **Proposed indication**

Solid tumours

### **EMA/CAT conclusion**

On the basis that the product:

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(a) contains somatic cells that have been subject to substantial manipulation, through differentiation, stimulation and in vitro expansion so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered;

(b) is administered to human beings with a view to treating solid tumours, i.e. a disease, through the pharmacological, immunological or metabolic action of its cells;

(c) does not include a medical device or an active implantable device,

the EMA/CAT considers that the Product falls within the definition of a Somatic Cell Therapy Medicinal Product.