EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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.

This scientific recommendation is not binding and is without prejudice to any decision taken by Member State competent authorities on matters falling within their own remits.

Brief descriptor (or name when available) of the proposed active substance

EBV specific T Lymphocytes

Brief description of the proposed finished product

EBV-specific T cells in suspension in human albumin

Proposed indication

Prophylactic or curative adoptive immunotherapy of EBV-associated malignant diseases

EMA/CAT conclusion

On the basis that:

-the product consists of viable 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,

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-the product is to be administered to human beings with a view to treating and preventing a disease through the pharmacological, immunological or metabolic action,

-EBV specific T lymphocytes are not to be administered to human beings with a view to regenerating, repairing or replacing a human tissue,

the EMA/CAT considers that the product falls within the definition of a somatic cell therapy medicinal product, as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007 and defined in Part IV of Annex I to Directive 2001/83/EC.