EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 April 2016
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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)

Ex vivo expanded autologous Epstein-Barr Virus specific T-cells derived from peripheral blood mononuclear cells

Brief description of the finished product

Autologous T cells in injectable saline suspended in a cryopreservation medium

Proposed indication

Treatment of Epstein-Barr Virus (EBV) positive malignancies

EMA / CAT conclusion

The committee adopted on 3rd March 2016 the following scientific recommendation.

On the basis that the product:

- consists of 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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- is presented as having properties for, or is administered to human beings with a view to treating a disease through the immunological action of its cells

the EMA/CAT considers that the product falls within the definition of a somatic cell therapy medicinal product.