



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 May 2015
EMA/556392/2015
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

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Brief description (or name where available) of the active substance(s)

Irradiated plasmacytoid dendritic cell line loaded with peptides from tumour antigens

Brief description of the finished product

Suspension of cells for subcutaneous injection

Proposed indication

Treatment of metastatic cancer



EMA/CAT conclusion

On the basis that:

- the product consists of cells of human origin that have been subject to substantial manipulation, so that the biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered;
- the product is to be administered to human beings with a view to treating a disease through the immunological action.

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.