EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 January 2015
EMA/555336/2015
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

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

The product is viable, human, autologous, tumour-infiltrating lymphocytes (TIL) derived from metastatic melanoma (MM).

Brief description of the finished product

Living, autologous, melanoma-derived lymphocytes (CD3+) suspended in buffered saline containing human serum albumin.

Proposed indication

Therapeutic treatment of metastatic melanoma in patients pre-conditioned with chemotherapy and undergoing concomitant interleukin-2 (IL-2) treatment.

EMA/CAT conclusion

On the basis that:

- The product consists of viable cells that have been subject to substantial manipulation (i.e. enzymatic digestion of tumour tissue followed by *ex vivo* expansion) so that biological

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characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered;

- The product is presented as having properties for treating a disease in human beings;
- The product is presented as acting via immunological means.

The EMA/CAT considers that the product falls within the definition of somatic cell therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.