4 June 2013
EMA/341778/2013
Patient Health Protection

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.

Short description of the proposed active substance

Human autologous tumour-infiltrating lymphocytes (TIL).

Brief description of the proposed finished product

More than one billion of human autologous tumour–infiltrating lymphocytes suspended in 4% human serum albumin.

Proposed indication

Treatment of Stage III melanoma with one invaded lymph node

EMA/CAT comment

Consideration of Article 1(2) of Directive 2001/83/EC

- The product consists of tumour-infiltrating lymphocytes which can be considered a 'substance' in the meaning of the pharmaceutical legislation (in accordance with article 1(3) of Directive 2001/83/EC), administered to humans with a view of restoring physiological functions by exerting an immunological action.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

- According to Article 1(2), the restoration, correction or modification of the physiological function is to be mediated by the substances that exert "a pharmacological, immunological or metabolic action". As the product consists of tumour-infiltrating lymphocytes it can be agreed that the product acts via immunological means.
- The product is presented as having properties for treating disease in human being. It is intended to be used for treating patients with stage III melanoma with one invaded lymph node, by exerting an anti-cancer immunological action.

Fulfilment of Article 2(1) of Regulation (EC) No 1394/2007

- The product consists of viable human autologous tumour-infiltrating T cells.
- The product is expanded ex vivo from tumour tissue, which can be considered as a substantial manipulation of the cells.
- The product is presented as acting via immunological means.

Based on the above considerations, it is considered that TILs falls within the definition of somatic cell therapy as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.

EMA/CAT conclusion

On the basis that:

- The product consists of viable cells that have been subject to substantial manipulation (i.e. expanded ex vivo from tumour tissue) so that biological 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 being

- 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.