EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2013
EMA/50963/2013
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 descriptor (or name when available) of the proposed active substance

The active substance is a mixture of autologous dendritic cells (DCs) pulsed with a Non structural 3 (NS3) protein fragment of Hepatitis C Virus (HCV) and activated T-cells.

Brief description of the proposed finished product

Cell suspension formulated in culture medium.

Proposed indication

Treatment of patients with chronic HCV infection.

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EMA/CAT comment

Consideration of Article 1(2) of Directive 2001/83/EC (definition of medicinal product – see Annex A)

- The product consists of ex vivo pulsed autologous dendritic cells and T cells 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 to modifying functions by exerting an immunological action.
- The product is presented as having properties for treating disease in human being.
- According to Article 1(2), the restoration, correction or modification of the physiological function is to be mediated by the substances that exert an immunological or metabolic action. As the product consists of activated autologous dendritic cells, it can be agreed that the product acts via immunological means.

Fulfilment of Article 2(1) of Regulation (EC) No 1394/2007 (definition of advanced therapy medicinal product – see Annex A)

- 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.

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

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

EMA/CAT conclusion

On the basis that,

- The product is composed of viable activated autologous dendritic cells and T cells

- 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.

- The product is presented as having properties for, or is used in or administered to human beings with a view to treating a disease through immunological action of its cells.

- The product does not contain any medical device.

The EMEA/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.