



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 May 20133
EMA/277503/2013
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

Naturally-occurring allogeneic donor lymphocytes (derived from a leukapheresis, bone marrow or a whole blood product) that are enriched for antigen-specific CD4+ and CD8+ T cells using the Cytokine Capture system (IFN-gamma).

Brief description of the proposed finished product

Naturally-occurring allogeneic donor lymphocytes enriched for antigen-specific CD4+ and CD8+ T cells in 0.9% NaCl with 4% HSA

Proposed indication

Treatment of therapy-refractory infectious and infection-related diseases
Pre-emptive and prophylactic treatment of infectious and infection-related diseases

EMA/CAT comment

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

- Antigen specific T-cells, isolated using the Cytokine Capture System (IFN-gamma), can be considered as 'substance' in the meaning of the pharmaceutical legislation (in accordance



with Article 1(3) of Directive 2001/83/EC), which is administered to humans with a view to restoring physiological functions

-The product is presented as having properties for treating and preventing disease in human being: treatment of therapy-refractory infectious and infection-related diseases and Pre-emptive and prophylactic treatment of infectious and infection-related diseases.

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". Antigen specific T-cells, isolated using the Cytokine Capture System (IFN-gamma), fulfil the conditions expressed in Article 1(2) as they act via immunological means.

Antigen specific T-cells, isolated using the Cytokine Capture System (IFN-gamma), should thus be considered as a medicinal product.

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

- The manufacturing process induces cell activation which has been considered as a substantial manipulation.
- The cells have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered and
- The cells are presented as having properties for, or is used in or administered to human beings with a view to treating or preventing a disease through the immunological action of its cells

Based on the above considerations, it is considered that Antigen specific T-cells, isolated using the Cytokine Capture System (IFN-gamma), do fall within the definition of an advanced therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007 and more specifically under the scope of the definition of a somatic cell therapy medicinal product.

EMA/CAT conclusion

On the basis of that,

- The product is to be administered to human beings with a view to treating or preventing a disease through the pharmacological, immunological or metabolic action,
- The product consist of viable cells that have been subject to substantial manipulation,
- The antigen-specific T cells biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered

The EMA/CAT considers by majority that Antigen specific T-cells, isolated using the Cytokine Capture System (IFN-gamma), fall within the definition of an advanced therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007 and more specifically under the scope of the definition of a somatic cell therapy medicinal product.