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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

Autologous CD4+ T cells targeted to cells presenting class II restricted epitopes

Brief description of the proposed finished product

Suspension of Autologous CD4+ T cells targeted to cells presenting class II restricted epitopes

Therapeutic claim

Autoimmune diseases with MHC restricted specific immunity e.g. multiple sclerosis, type I diabetes or graft rejection.

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

EMA/CAT comment

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

- The product consists of *in-vitro* expanded autologous CD4+ T cells targeted to cells presenting class II restricted epitopes, 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 Multiple Sclerosis.
- 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 "a pharmacological, immunological or metabolic action". As the product consists of autologous CD4+ T cells targeted to cells presenting class II restricted epitopes, 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. Naïve CD4+ T cells are first purified from the peripheral blood mononuclear cell pool and then primed and expanded by incubation with *in vitro* derived dendritic cells pulsed with a peptide linked to a thioredox motif.

Based on the above considerations, it is considered that the product falls within the definition of an advanced therapy medicinal product.

EMA/CAT conclusion

On the basis that:

-The product consists of autologous CD4+ T cells that have been subject to substantial manipulation.

-The product is 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.