EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 dendritic cells activated with autologous oncolysate.

Brief description of the proposed finished product

An autologous dendritic cell immunotherapeutic comprising of autologous dendritic cells activated with autologous oncolysate.

Proposed indication

Glioma

EMA/CAT comment

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

- The product contains autologous dendritic cells pulsed with an autologous oncolysate and is presented as having properties for treating a disease in human beings

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

- The autologous dendritic cells pulsed with the autologous oncolysate 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 human beings with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action

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

- The product contains viable cells.
- The autologous dendritic cells are produced from monocytes by incubation *in vitro* with appropriate differentiation factors. After differentiation, dendritic cells are pulsed with an autologous oncolysate and induced to mature by the addition of other factors. It can be concluded that the cells are subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been achieved and can thus be considered as engineered cells.
- The product is administered to humans with the view to treat a disease.

Based on the above considerations, it is considered that the product falls within the definition of an advanced therapy medicinal product and more specifically a somatic cell therapy product.

EMA/CAT conclusion

On the basis that:

-the product consists of viable 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 to be administered to human beings with a view to treating a disease through the pharmacological, immunological or metabolic action,

the EMA/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 and defined in Part IV of Annex I to Directive 2001/83/EC.