17 October 2012
EMA/498937/2012
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

Allogenic and autologous haptenised and irradiated cells and corresponding cell lysates derived from the tumour mass of patients diagnosed with Glioblastoma multiforme.

Brief description of the proposed finished product

The finished product is composed of four different active substances that are formulated individually:

1/- Haptenised and irradiated human Autologous Glioblastoma tumour cells

2/- Haptenised and irradiated human Allogeneic Glioblastoma tumour cells

3/- Haptenised and irradiated cell lysates from human Autologous Glioblastoma tumour cells

4/- Haptenised and irradiated cell lysates from human Allogeneic Glioblastoma tumour cells

Proposed indication

The finished product is proposed to treat Glioblastoma multiforme

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EMA/CAT comment

Consideration of Article 1(2) of Directive 2001/83/EC as referred to in Article 2 of Regulation (EC) No. 1394/2007 (definition of medicinal product – see Annex A)

- The product consists of haptenised and irradiated human autologous and allogeneic tumour cells, and derived cell lysates can be considered a combination of 'substances' 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 restoring physiological function(s) by exerting a metabolic, immunological and/or a pharmacological action.
- The product is presented as having properties for treating or preventing 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 haptenised and irradiated human autologous or allogeneic tumour cells and derived cell lysates, 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)

- Taking into consideration the definition of a somatic cell therapy medicinal product as provided in Directive 2009/120/EC amending Directive 2001/83/EC Part IV of Annex I and referred to in Regulation (EC) 1394/2007, this product is considered to be a product which contains or consists of human cells that have been subject to substantial manipulation so that the biological characteristics, physiological functions or structural properties relevant to the intended clinical use have been altered.
- Furthermore, tumour cells can be considered not intended to be used for the same essential function in the recipient as in the donor. They are rather intended to be used to exert an immunological action to prevent and to treat Multiform Gliobastoma in human beings.

  Based on the above considerations, it is considered that the product does fall within the definition of an advanced 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 indicated to treat patients with Glioblastoma multiforme through immunological action
- The product contains cells that have been haptenised to obtain an immunological effect, and irradiated to render them non-tumorigenic,.
- The cells in the product can be considered as not intended to be used for the same essential function in the recipient as in the donor.

The EMEA/CAT considers that the product does fall within the definition of a somatic cell therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.