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

Attenuated Salmonella typhi Ty21a strain transfected with a plasmid vector encoding for the human vascular endothelial growth factor receptor 2.

Brief description of the proposed finished product

Aqueous suspension of attenuated Salmonella typhi Ty21a strain transfected with a plasmid vector encoding for the human vascular endothelial growth factor receptor 2 in a formulation solution.

Proposed indication

Treatment of solid malignancies with or without metastases

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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 an attenuated strain of Salmonella enterica serovar typhi Ty21a carrying multiple copies of a plasmid DNA, encoding an expression cassette of the human Vascular Endothelial Growth Factor-Receptor 2 (VEGFR-2). It can thus be considered a 'substance' in the meaning of the pharmaceutical legislation (in accordance with article 1(3) of Directive 2001/83/EC).

- The product is indicated for the treatment of solid malignancies with or without metastases.

- According to Article 1(2), any substance or combination of substances presented as having properties for treating or preventing disease in human is a medicinal product. As the product is considered as a "substance", which is "having properties to treating disease in human", it can be agreed that the product is a medicinal product.

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

- The product consists of an attenuated strain of Salmonella enterica Ty21a carrying the plasmid DNA encoding (VEGFR-2). Thus the active substance complies with the definition of a Gene Therapy Medicinal Product as described in 2001/83/EC, Annex I, Part IV, as amended (implementing Directive 2009/120/EC) section 2.1 (a).

- The therapeutic effect of the product relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence, as described in 2001/83/EC, Annex I, Part IV, as amended (implementing Directive 2009/120/EC) section 2.1 (b).

- The product does not incorporate as an integral part of the product any medical devices and/or active implantable medical devices, as defined in Article 2(1)(d) of Regulation (EC) No 1394/2007.

Based on the above considerations, it is considered that the product falls within the definition of an Advanced Therapy Medicinal Product, and specifically a Gene Therapy Medicinal Product as defined in Article 2(1) (a) of Regulation (EC) No 1394/2007 and Annex I Part IV of Directive 2001/83/EC, as amended (implementing Directive 2009/120/EC).

EMA/CAT conclusion

On the basis that,

-The product is indicated for the treatment of solid malignancies with or without metastases.

-The product consists of an attenuated strain of Salmonella enterica Ty21a carrying the plasmid DNA, encoding (VEGFR-2). Thus the active substance complies with the definition of a Gene Therapy Medicinal Product as described in 2001/83/EC, Annex I, Part IV, as amended (implementing Directive 2009/120/EC) section 2.1 (a).

-The therapeutic effect of the product relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence, as described in 2001/83/EC, Annex I, Part IV, as amended (implementing Directive 2009/120/EC) section 2.1 (b).

-The product does not incorporate as an integral part of the product any medical devices and/or active implantable medical devices, as defined in Article 2(1)(d) of Regulation (EC) No 1394/2007.

The EMA/CAT considers that the product falls within the definition of a Gene Therapy Medicinal Product as defined in Article 2(1) (a) of Regulation (EC) No 1394/2007 and Annex I Part IV of Directive 2001/83/EC, as amended (implementing Directive 2009/120/EC).