22 November 2016
EMA/761630/2016
Inspections Human Medicines Pharmacovigilance Division
Committees and Inspections Department

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.

It is stressed that the scientific recommendation on advanced therapy classification does not amount to any endorsement of the plausibility of the product, including the mode of action or therapeutic indication(s) claimed by the applicant.

Brief description (or name when available) of the active substance(s)

A recombinant replicating vaccinia viral vector (*rilimogene galvacirepvec*) and a recombinant non-replicating fowlpox viral vector (*rilimogene glafolivec*), both expressing a modified human Prostate Specific Antigen (PSA) and three human costimulatory molecules (LFA-3, ICAM-1, and B7.1).

Brief description of the finished product

Suspensions for subcutaneous injection.

Proposed indication

Treatment of metastatic, castrate-resistant prostate cancer.

EMA / CAT conclusion

The committee adopted on 4 November 2016 the following recommendation.

On the basis that the product:

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- the active substances contain recombinant nucleic acids and are administered to human beings with a view to add a genetic sequence;
- its therapeutic effect relates directly to the protein products of genetic expression of the sequence it contains,

the EMA/CAT considers that the Product falls within the definition of a gene therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) 1394/2007.