EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management & Business Support Division
Scientific Committee Support 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

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

The product is an oncolytic virus derived from a genetically modified type 1 herpes simplex virus (HSV-1).

Brief description of the finished product

Viral solution for injection of HSV-1 derived oncolytic virus.

Proposed indication

Treatment of advanced pancreatic cancer and / or unresectable hepatocellular carcinoma.

EMA/CAT conclusion

On the basis that:

- The product contains a biological medicinal product as the active substance;
- The active substance is a recombinant nucleic acid administered to human beings with a view to regulating and adding a genetic sequence;

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- Its therapeutic effect relates directly to the product of the genetic expression of this sequence,

the EMA/CAT considers that the Product Myb34.5 falls within the definition of a gene therapy medicinal product.