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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 description of the proposed active substance

The product is an adenoviral vector derived from subgroup C chimpanzee adenovirus ChAd3 expressing the Non structural region (NS) of hepatitis C virus (HCV) in which a mutation has been introduced. Three amino acids, in the catalytic site of NS5B, were replaced with an inactive amino acids sequence, called NSmut

Brief description of the proposed finished product

Sterile suspension of 5.10^{10} viral particles in 0.5ml of A195 buffer supplied in 2ml vial

Proposed indication

Prevention and Treatment of hepatitis C (HCV) and HCV-induced hepatocellular carcinoma

EMA/CAT comment

Consideration of Article 1(2) of Directive 2001/83/EC

The product consist of an adenoviral vector derived from subgroup C chimpanzee adenovirus ChAd3 expressing the Non structural region (NS3, NS4A, NS4B, NS5A and NS5B) of hepatitis C virus (HCV), can be considered as a "substance" in the meaning of the pharmaceutical legislation (in accordance

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with article 1(3) of the Directive 2001/83/EC), which is administered to humans with a view to restoring physiological functions.

The product is presenting as having properties for treating a disease in human beings: Prevention and treatment of hepatitis C (HCV) and HCV-induced hepatocellular carcinoma

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".

AdCh3NSmut1 fulfil the conditions expressed in the article 1(2) of Directive 2001/83/EC, as it is presented as acting via immunological means.

Based on the above considerations, it is considered that AdCh3NSmut1 falls within the definition of a medicinal product

Fulfilment of Article 2(1) of Regulation (EC) No 1394/2007

The product is a vectored vaccine against hepatitis C virus (HCV). The mechanism of action is based on the induction of a potent T-cell immune response against the non-structural proteins of the HCV virus.
The product is intended to be administered prophylactically to the patient in view of preventing or treating HCV infection as well as HCV- induced hepatocellular carcinoma
Based on the above considerations, it is considered that it is a vaccine administered to the patient to prevent and/or to treat an infectious disease.

With reference to Section 2.1 of Part IV of Annex I to Directive 2001/83/EC, which stipulates that gene therapy medicinal products shall not include vaccines against infectious disease, the product does therefore not 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 of that,

With reference to Section 2.1 of Part IV of Annex I to Directive 2001/83/EC, which stipulates that gene therapy medicinal products shall not include vaccines against infectious disease, the EMA/CAT considers that the product does not fall within the definition of an advanced therapy medicinal product as provided in the article 2(1)(a) of the Regulation (EC) No 1394/2007.