EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2014
EMA/CHMP/688255/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Viekirax

ombitasvir / paritaprevir / ritonavir

On 20 November 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Viekirax (12.5 mg of ombitasvir, 75 mg of paritaprevir and 50 mg of ritonavir), film-coated tablets intended for the treatment of chronic hepatitis C in adults in combination with other medicinal products. The applicant for this medicinal product is AbbVie Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substances of Viekirax are ombitasvir, an inhibitor of HCV non-structural protein NS5A, which is essential for the viral replication, paritaprevir, an inhibitor of the nonstructural protein NS3/4A protease, also essential for the viral replication, and ritonavir, a potent cytochrome P450 3A4 inhibitor used as a pharmacokinetic enhancer.

The benefits with Viekirax used in combination with other medicinal products is its ability to inhibit viral replication in infected host cells which can lead to the eradication of the virus, correlating to a cure of chronic hepatitis C virus (HCV) infection, in both non-cirrhotic and compensated cirrhotic patients with genotype 1a/1b and 4 HCV infection. The most common side effects are fatigue and nausea.

A pharmacovigilance plan for Viekirax will be implemented as part of the marketing authorisation.

The approved indication is: "Viekirax is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults (see sections 4.2, 4.4, and 5.1).

For hepatitis C virus (HCV) genotype specific activity, see sections 4.4 and 5.1."

It is proposed that Viekirax be prescribed by physicians experienced in the treatment of the chronic hepatitis C infection.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Viekirax and therefore recommends the granting of the marketing authorisation.