20 November 2014
EMA/CHMP/688227/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Exviera

dasabuvir

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 Exviera, 250 mg 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 substance of Exviera is dasabuvir sodium, a non-nucleoside inhibitor of the HCV RNA-dependent RNA polymerase encoded by the NS5B gene.

The benefits with Exviera used in combination with other medicinal products are 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 HCV infection. The most common side effects are fatigue and nausea.

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

The approved indication is: "Exviera 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 Exviera be prescribed by physicians experienced in the treatment of the chronic hepatitis C infection.

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

[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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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 Exviera and therefore recommends the granting of the marketing authorisation.