10 November 2016
EMA/704543/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vemlidy

tenofovir alafenamide

On 10 November 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vemlidy, intended for the treatment of chronic hepatitis B. The applicant for this medicinal product is Gilead Sciences International Ltd.

Vemlidy will be available as 25 mg film-coated tablets. The active substance of Vemlidy is tenofovir alafenamide, a nucleotide reverse transcriptase inhibitor (ATC code: J05AF13). Tenofovir alafenamide is a substrate and competitive inhibitor of HBV reverse transcriptase. After phosphorylation, it is incorporated into the viral DNA chain, resulting in chain termination.

The benefits with Vemlidy are its ability to achieve a sustained antiviral response in treatment-naive and treatment-experienced patients. The most common side effect is headache. Vemlidy has low impact on renal safety and bone mineral density compared to the licensed tenofovir disoproxil.

The full indication is: "Vemlidy is indicated for the treatment of chronic hepatitis B in adults and adolescents (aged 12 years and older with body weight at least 35 kg)". It is proposed that Vemlidy be prescribed by physicians experienced in the management of chronic hepatitis B.

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.

[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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