22 June 2017
EMA/CHMP/347210/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vosevi

sofosbuvir / velpatasvir / voxilaprevir

On 22 June 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vosevi, intended for the treatment of chronic hepatitis C. Vosevi was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is Gilead Sciences International Ltd.

Vosevi is a fixed-dose combination of three direct-acting antivirals, sofosbuvir, velpatasvir and voxilaprevir. It will be available as film-coated tablets (containing 400 mg sofosbuvir, 100 mg velpatasvir and 100 mg voxilaprevir). The active metabolite of sofosbuvir is an inhibitor of the hepatitis C virus (HCV) NS5B RNA polymerase, velpatasvir targets the NS5A protein of the virus and voxilaprevir inhibits the non-structural protein NS3/4A protease; all these proteins are essential for viral replication.

The benefits with Vosevi are that it is highly effective against all genotypes of HCV and can be used in patients in whom prior treatment with other direct-acting antivirals has failed. The most common side effects are headache, diarrhoea and nausea.

The full indication is: "Vosevi is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults".

It is proposed that Vosevi be prescribed by physicians experienced in the management of patients with HCV 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 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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact