21 March 2013
EMA/CHMP/158160/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Stribild

Elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil

On 21 March 2013 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Stribild, 150 mg / 150 mg / 200 mg / 245 mg, film-coated tablets intended for treatment of human immunodeficiency virus 1 (HIV 1) infection in adults aged 18 years and over who are antiretroviral treatment-naïve or are infected with HIV 1 without known mutations associated with resistance to any of the three antiretroviral agents in Stribild (see section 4.2, 4.4 and 5.1). The applicant for this medicinal product is Gilead Sciences International 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 Stribild are elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil , an antiviral for treatment of HIV infections, combinations (ATC code 05AR 09). Elvitegravir is an HIV-1 integrase strand transfer inhibitor (INSTI), cobicistat enhances the systemic exposure of elvitegravir, emtricitabine is a nucleoside analogue of cytidine and tenofovir, is a nucleoside monophosphate (nucleotide) analogue of adenosine monophosphate.

The benefits with Stribild are its ability to reduce the viral load to undetectable levels (< 50 HIV-1 RNA copies/ml. The most common side effects are hypophosphataemia, headache, dizziness, diarrhoea, vomiting, nausea, rash, asthenia and elevated creatine kinase. The types of renal adverse reactions seen with Stribild were consistent with previous experience with tenofovir disoproxil fumarate. There are currently inadequate data to determine whether co-administration of tenofovir disoproxil fumarate and cobicistat is associated with a greater risk of renal adverse reactions compared with regimens that include tenofovir disoproxil fumarate without cobicistat.

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

The approved indication is: "Stribild is indicated for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years and over who are antiretroviral treatment-naïve or are

[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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infected with HIV-1 without known mutations associated with resistance to any of the three antiretroviral agents in Stribild (see sections 4.2, 4.4 and 5.1).".

It is proposed that Stribild therapy should be initiated by a physician experienced in the management of HIV 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.

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