25 July 2013
EMA/CHMP/413499/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tybost

cobicistat

On 25 July 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 Tybost, 150 mg, Film-coated tablet intended for use as a pharmacokinetic enhancer of the human immunodeficiency virus-1 (HIV-1) protease inhibitors atazanavir and darunavir in adults. 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 substance of Tybost is cobicistat, a PK enhancer (V03AX03) and is a selective, mechanism-based inhibitor of cytochromes P450 of the CYP3A subfamily.

The benefits with Tybost are its ability to inhibit CYP3A-mediated metabolism and to enhance the systemic exposure of CYP3A substrates (such as atazanavir or darunavir) that have limited oral bioavailability and a short half-life due to CYP3A-dependent metabolism. The most common side effects with cobicistat-boosted atazanavir are associated with elevated bilirubin levels.

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

The approved indication is: "Tybost is indicated as a pharmacokinetic enhancer of atazanavir 300 mg once daily or darunavir 800 mg once daily as part of antiretroviral combination therapy in human immunodeficiency virus-1 (HIV-1) infected adults". It is proposed that Tybost be prescribed by physicians 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.

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