25 September 2014
EMA/CHMP/578742/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

REZOLSTA

Darunavir / cobicistat

On 25 September 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 REZOLSTA (800 mg/150 mg), film-coated tablet intended for the treatment of antiretroviral therapy (ART)-naïve adults and ART-experienced adults with no darunavir (DRV) resistance associated mutations (RAMs). The applicant for this medicinal product is Janssen-Cilag International N.V.

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.

REZOLSTA is a fixed-dose combination of the antiretroviral medicinal product darunavir and the pharmacokinetic enhancer cobicistat. The active substance of REZOLSTA is darunavir, an HIV-1 protease inhibitor [Antivirals for systemic use, antivirals for treatment of HIV infection, combinations (ATC code: J05AR14)].

The benefits with REZOLSTA are its ability to provide sustainable virological suppression if given as part of combination with other antiretroviral medicinal products for treatment of HIV-1 infection. The most common side effects are diarrhoea, nausea, and rash. A pharmacovigilance plan for REZOLSTA will be implemented as part of the marketing authorisation.

The approved indication is: "REZOLSTA, is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus 1 (HIV 1) infection in adults aged 18 years or older. Genotypic testing should guide the use of REZOLSTA (see sections 4.2, 4.3, 4.4 and 5.1)".

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 REZOLSTA and therefore recommends the granting of the marketing authorisation.