15 October 2020
EMA/CHMP/455296/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rekambys

rilpivirine

On 15 October 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rekambys, intended for the treatment of human immunodeficiency virus type-1(HIV-1) infection in combination with cabotegravir injection.

The applicant for this medicinal product is Janssen-Cilag International N.V.

Rekambys will be available as a prolonged-release suspension for injection (600 and 900 mg). The active substance of Rekambys is rilpivirine, a direct -acting antiviral non-nucleoside reverse transcriptase inhibitor (NRTI) (ATC code: J05AG05). Rilpivirine triggers a non-competitive inhibition of HIV-1 reverse transcriptase. It should always be used in combination with cabotegravir injection, another long-acting antiretroviral.

The benefits with Rekambys used in combination with cabotegravir injection are its formulation and delivery as a prolonged-release suspension for injection which reduces dosing frequency to once a month or every two months compared with daily oral antiretrovirals. A reduced dosing schedule may increase patient satisfaction and compliance.

The most common side effects observed in clinical trials for this regimen (Rekambys plus cabotegravir injection) were injection site reactions followed by headache, pyrexia, nausea, fatigue, asthenia, myalgia and dizziness.

In addition, there could be a risk of emergence of resistance associated with this long-acting regimen when it is not used correctly or not adhered to. Some measures have been put in place to minimise this risk (see sections 4.2, 4.4 and 5.1).

The full indication is:

> "Rekambys is indicated, in combination with cabotegravir injection, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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resistance to, and no prior virological failure with, agents of the NNRTI and INI class (see sections 4.2, 4.4 and 5.1).

Rekambys should 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.