15 October 2020
EMA/CHMP/447977/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vocabria

cabotegravir

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 Vocabria intended for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in combination with rilpivirine injection.

The applicant for this medicinal product is ViiV Healthcare B.V.

Vocabria will be available as film-coated tablets (30 mg) and as a prolonged-release suspension for injection (400 and 600 mg). The active substance of Vocabria is cabotegravir, a direct- acting antiviral (ATC code: J05AJ04) known as an integrase strand transfer inhibitor (INI). Cabotegravir inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral deoxyribonucleic acid (DNA) integration which is essential for the HIV replication cycle. Vocabria is to be used in combination with Rekambys (rilpivirine), another long-acting antiretroviral.

The benefits with Vocabria used in combination with Rekambys are its formulation and delivery (as a prolonged-release suspension for injection) which reduce 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 (Vocabria plus Rekambys) 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:

> "Vocabria injection is indicated, in combination with rilpivirine 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 resistance to, and no prior virological failure with agents of the NNRTI and INI

[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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class (see sections 4.2, 4.4 and 5.1).

Vocabria 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.