20 July 2023
EMA/327881/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Apretude

cabotegravir

On 20 July 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Apretude, intended for prevention of sexually acquired HIV-1 in combination with safer sex practices. The applicant for this medicinal product is ViiV Healthcare B.V.

Apretude will be available as a 30 mg film-coated tablet and a 600 mg prolonged-release suspension for injection. The active substance of Apretude is cabotegravir, an antiviral for systemic use (ATC code: J05AJ04). Cabotegravir is an integrase inhibitor of HIV-1 which inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral DNA integration, which is essential for the HIV replication cycle.

The benefit of Apretude was a demonstrated superiority of injections every 2 months over a daily oral regimen of tenofovir disoproxil fumarate plus emtricitabine (TDF/FTC) in preventing acquisition of HIV-1 infection, with a 69% and an 90% risk reduction, as shown in two double-blind safety and efficacy studies. The most common side effects are injection site reactions, headache, diarrhoea, and increased transaminase levels.

The full indication is:

> Apretude is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents, weighing at least 35 kg (see sections 4.2, 4.4 and 5.1).

Apretude should be prescribed by physicians experienced in the treatment of HIV.

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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