24 July 2025
EMA/CHMP/243442/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Yeytuo

lenacapavir

On 24 July 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the granting of a marketing authorisation for the medicinal product Yeytuo (lenacapavir) intended for the prophylaxis against sexually acquired human immunodeficiency virus type 1 (HIV-1) infection. Yeytuo was reviewed under EMA's accelerated assessment programme.

Yeytuo will be available as a 464 mg solution for injection and as 300 mg film-coated tablets, both are essential for the treatment course. After the initiation dose (consisting of both injection and tablets), the frequency of injections is once every 6 months. The active substance of Yeytuo is lenacapavir, an antiviral for systemic use. Lenacapavir is a multistage, selective inhibitor of HIV-1 capsid function that ultimately inhibits HIV-1 replication.

The main evidence of efficacy of Yeytuo was based on two phase 3 clinical trials: PURPOSE 1, involving adolescent (from 16 years of age) and adult women, and PURPOSE 2, involving adolescent (over 16 years of age) and adult men and gender-diverse persons. The results showed a reduction in the incidence of HIV-1 infections with Yeytuo compared with once daily emtricitabine/tenofovir alafenamide (FTC/TDF) (PURPOSE 1: rate ratio (RR): 0.000, 95% confidence interval (CI): 0.000, 0.101; p <0.0001; PURPOSE 2: RR: 0.111; 95% CI: 0.024, 0.513; p = 0.00245). The most relevant safety concerns were slow or non-resolving injection site nodules and indurations, and the most commonly reported adverse reactions were local injection site reactions, headache, nausea, and diarrhoea.

The full indication for Yeytuo solution for injection is:

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

The full indication for Yeytuo film-coated tablets is:

[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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Yeytuo tablet is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in adults and adolescents with increased HIV-1 acquisition risk, weighing at least 35 kg for:

- oral loading
- oral bridging

(see sections 4.2, 4.4 and 5.1).

Yeytuo should be prescribed by a healthcare professional experienced in the management of HIV prevention.

Detailed recommendations for the use of this product are described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.

This report summarises the scientific review leading to the opinion adopted by the Committee for Medicinal Products for Human Use (CHMP).