23 June 2022
EMA/CHMP/562259/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sunlenca

lenacapavir

On 23 June 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sunlenca, intended for the treatment of adults with multidrug-resistant human immunodeficiency virus type 1 (HIV-1) infection.

The applicant for this medicinal product is Gilead Sciences Ireland UC.

Sunlenca will be available as a 300 mg film-coated tablet and a 464 mg solution for injection. The active substance of Sunlenca is lenacapavir, an antiviral for systemic use (ATC code: J05AX). Lenacapavir is a selective inhibitor of HIV-1 capsid function that directly binds to the interface between capsid protein (CA) subunits and inhibits HIV-1 replication by interfering with multiple, essential steps of the viral lifecycle.

The main benefits of Sunlenca are its ability to sustainably reduce HIV-1 viral load and keep it at a low level and the increase of the CD4 cell count, as shown in the CAPELLA study in 72 patients with multiclass resistant (MDR) HIV-1.

The most common adverse reactions in observed in this trial were injection site reactions and nausea

The full indication is:

> **Sunlenca injection**, in combination with other antiretroviral(s), is indicated for the treatment of adults with multidrug-resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen (see sections 4.2 and 5.1).
>
> **Sunlenca tablet**, in combination with other antiretroviral(s), is indicated for the treatment of adults with multidrug-resistant HIV-1 infection for whom it is otherwise not possible to construct

[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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a suppressive anti-viral regimen, for oral loading prior to administration of long-acting lenacapavir injection (see sections 4.2 and 5.1).

Sunlenca should be prescribed by physicians experienced in the treatment of HIV. Prior to starting lenacapavir, the healthcare professional should carefully select patients who agree to the required injection schedule. To help maintain viral suppression and reduce the risk of viral rebound and potential development of resistance associated with missed doses, the healthcare professional should also counsel patients about the importance of adherence to both the scheduled dosing visits and the optimised background regimen.

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.