

Category

Best Pharmaceutical Product

Drug / Device Name

Sunlenca®

Compound/ Tech Name

Lenacapavir

Trade Name

Sunlenca®

Date of Approval

2022-08-19

Indications

Sunlenca (300 mg tablet and 463.5 mg/1.5 mL injection) is a first-in-class, long-acting human immunodeficiency virus type 1 (HIV-1) capsid inhibitor approved for the treatment of HIV-1 infection, in combination with other antiretroviral(s), in people who are heavily treatment-experienced with multi-drug resistant HIV-1.

Therapeutic Categories

human immunodeficiency virus (HIV)

Attached Files:

- 20230626_Gilead Prix Galien Application_Lenacapavir_SUBMIT.docx
- 20230626_Product abstract for LEN_Prix Galien_SUBMIT.docx

Background information and need for drug/device

HIV remains a global public health threat. Contemporary highly efficacious single-tablet regimens have resulted in simplified dosing compared to the complex “cocktail” regimens of the early days of the epidemic and sustained virologic suppression arrests HIV disease progression and averts onward HIV transmission. Despite these game-changing advances, ending HIV as a public health threat remains out of reach, as only two-thirds of people with HIV globally are virally suppressed and 1.5 million new infections occur each year. New approaches and continued innovation are needed, ensuring that no one is left behind and with a goal to bring about the end of the epidemic.

Although many people who are diagnosed with HIV today will be able to successfully manage their HIV with a single daily tablet, the subset of people with multi-drug resistant HIV (MDR HIV) require regimens with significantly more components and complex dosing; even with best available therapies, some with MDR HIV cannot achieve viral suppression, risking imminent morbidity and mortality. There is a critical need for new classes of antiretroviral therapies that are active against resistant variants of the virus with a novel mechanism of action.

Sunlenca (lenacapavir) is a first of its kind capsid inhibitor that provides a new option to help adults with MDR HIV achieve and maintain viral suppression. Its unique mode of action, picomolar potency, and long half-life, permitting dosing just once every six months, represent a monumental breakthrough for heavily treatment-experienced people with MDR HIV. Beyond the immediate impact for MDR HIV, the unique properties of lenacapavir serve as a foundation for a new era of long-acting, person-centric HIV treatment and prevention options that will meet the diverse needs of the people with and at risk for HIV.

History of the development of the drug/device

At Gilead, we believe it will be possible to end the HIV epidemic for everyone, everywhere. Long-acting options for HIV treatment and prevention will be the next wave of innovation needed to help address the differentiated needs and preferences of the diverse range of individuals and communities affected by the epidemic.

Lenacapavir was developed by Gilead and began its journey to patients over 16 years ago. Through incredible resilience and persistence, Gilead scientists developed and screened nearly 4,000 compounds to find GS-6207, a molecule with great antiviral potency, novel mechanism of action and long-acting properties, which would later become lenacapavir. Once identified our team worked with incredible speed and focus to bring Sunlenca to patients with only 3.5 years between filing the IND and its first new drug application.

In May 2019, the FDA granted Breakthrough Therapy Designation for the development of lenacapavir for the treatment of HIV-1 infection in heavily treatment-experienced patients with multi-drug resistance in combination with other antiretroviral drugs. In August 2022, lenacapavir was the first capsid inhibitor to gain regulatory approval with its authorization in the European Union. Lenacapavir is also approved in the United States, Australia, United Arab Emirates, Canada and the United Kingdom.

The approvals for Sunlenca are supported by data from the Phase 2/3 CAPELLA trial, which evaluated lenacapavir in combination with an optimized background regimen in people with multi-drug resistant HIV-1 who are heavily treatment experienced. CAPELLA participants had undergone previous treatment with a median of nine antiretroviral medications and all had sustained viral replication at the time of trial enrollment, with significant immunosuppression. The New England Journal of Medicine published the primary outcome results of the CAPELLA study in 2022.

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition

Advancing the next wave of transformational innovation in HIV requires putting people at the center of the research and development process. Our virology expertise and connections to the HIV community, enables us to bring forward person-centered innovation to help fulfill urgent, unmet needs in global health.

Lenacapavir is a breakthrough innovation with the potential to be a preferred and versatile foundational long-acting agent due to its therapeutic potency and range of dosing frequencies and routes of administration currently being studied. Lenacapavir is being developed as a foundation for Gilead's future HIV therapies with the goal of offering several long-acting options that help address individual patient needs and preferences that may help optimize outcomes and reduce burden of

care.

The unique multi-stage mechanism of action of lenacapavir is designed to provide a new avenue for the development of a long-acting treatment option for individuals with multi-drug resistant HIV whose virus no longer effectively responds to therapy. While most antivirals act on just one stage of viral replication, lenacapavir is designed to inhibit HIV at multiple stages of its lifecycle and has no known cross resistance exhibited in vitro to other existing drug classes.

Lenacapavir is being studied in multiple ongoing early and late-stage development programs and has the potential to offer a diverse set of person-centric options for treatment and prevention that could uniquely fit into the lives of people with HIV and people who would benefit from pre-exposure prophylaxis (PrEP)*.

Sunlenca represents a step change in HIV innovation, helping people with limited treatment options today, and with significant potential to help a range of people affected by HIV in the future. Only with innovations like Sunlenca that meet the diverse needs of the people with HIV, will we one day help end the epidemic for everyone, everywhere.

Please provide appropriate references (ie Pubmed links)

Segal-Maurer S, DeJesus E, Stellbrink HJ, Castagna A, Richmond GJ, Sinclair GI, Siripassorn K, Ruane PJ, Berhe M, Wang H, Margot NA, Dvory-Sobol H, Hyland RH, Brainard DM, Rhee MS, Baeten JM, Molina JM; CAPELLA Study Investigators. Capsid Inhibition with Lenacapavir in Multidrug-Resistant HIV-1 Infection. *N Engl J Med*. 2022 May 12;386(19):1793-1803. doi: 10.1056/NEJMoa2115542. PMID: 35544387.