Category

Best Pharmaceutical Product

General Information

Company Name *

GIlead Sciences

Product/Solution Name *

Yeztugo®

Compound/Tech Name*

Lenacapavir

Trade Name *

Yeztugo®

Corporate Name *

Gilead Sciences, Inc.

Date of Approval *

2025-06-18

Indications *

Yeztugo® (lenacapavir) injection, 463.5 mg/1.5 mL, is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents (>35kg) who are at risk for HIV-1 acquisition. Individuals must have a negative HIV-1 test prior to initiating Yeztugo.

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Therapeutic Areas *

Human Immunodeficiency Virus (HIV)

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*Kindly clearly label your files with company name and asset name.

Background information and need for drug / device
(please be as specific as possible in your description; limit 500 words)

More than 40 years since the beginning of the HIV/AIDS epidemic, HIV remains a public health threat in every corner of the world. About 1.3 million people acquire HIV each year despite major advances in

HIV treatment and prevention over just the past two decades-including the advent of a biomedical intervention called pre-exposure prophylaxis, or PrEP, which can significantly reduce the chances of acquiring HIV when taken as prescribed. In 2012, the U.S. Food and Drug Administration approved the first PrEP medication, once-daily oral Truvada®.

Since 2012, more than 6 million people are estimated to have started a form of PrEP. However, global PrEP use remains low-16.5% of the Joint United Nations Program on HIV/AIDS (UNAIDS) goal of 21.2 million users by 2025. In populations that are most disproportionately affected by HIV, uptake of and adherence to PrEP remains limited. Taking a daily pill for HIV prevention can be challenging to many individuals because of difficulties with daily compliance, competing life demands and the stigma of having pill bottles for an HIV-associated medication. Additionally, approximately 70% of oral PrEP users either discontinue or have poor adherence within 6 months of starting their regimens, which can significantly impact the real-world effectiveness of PrEP. This trend is consistent across multiple studies and populations, highlighting a major challenge in HIV prevention efforts and underscoring the need to develop new PrEP options-especially longer-acting options that do not depend on daily oral adherence or frequent injection visits.

Yeztugo® (lenacapavir) is a first-of-its-kind capsid inhibitor that provides a broad range of adolescents and adults a new, highly effective, safe and discreet option for PrEP that only needs to be administered twice a year, helping to increase PrEP adherence and persistence. Its unique scientific and dosing properties represent a historic breakthrough for individuals around the world who need or want PrEP.

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History of the development of the solution/product *
(please be as specific as possible in your description; 500 words)

At Gilead, our vision is to end the HIV epidemic for everyone, everywhere. Person-centric medications, especially long-acting options, for HIV treatment and prevention will be the next wave of innovation to help address the differentiated needs and preferences of the diverse range of individuals and communities affected by the epidemic.

Lenacapavir, developed over a dozen years of preclinical discovery by Gilead scientists, is the world's first viral capsid inhibitor. It began its journey to patients-as both an HIV treatment and prevention option-nearly 20 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, the Gilead team worked with incredible speed and focus to bring the first indication of lenacapavir, for treatment of highly treatment experienced patients in combination with an optimized background regimen and sold under the brand name Sunlenca®.

Gilead understood that lenacapavir also had the potential to be a highly effective prevention monotherapy, and in 2021 launched the PURPOSE trials-the most intentionally diverse HIV prevention trial program ever conducted. The program is designed to reflect often-overlooked populations disproportionately affected by HIV. The Phase 3 PURPOSE 1 trial was conducted in Sub-Saharan Africa

and enrolled cisgender women, who comprise more than half of all new HIV infections globally, and also intentionally recruited adolescent girls and pregnant and lactating women-an HIV prevention trial first. The Phase 3 PURPOSE 2 trial included geographically, racially and ethnically diverse cisgender men and transgender individuals in seven countries. In the two trials, >99.9% of people receiving lenacapavir remained HIV-free, an unprecedented outcome. Because of its high efficacy, novel dosing schedule and potential to reshape the global HIV epidemic, global public health leaders have described lenacapavir as a "miracle" and "game-changer," and the journal Science named lenacapavir its 2024 Breakthrough of the Year.

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

Yeztugo represents a remarkable innovation in HIV science and has been recognized globally by a wide range of public health leaders as "the drug that could revolutionize the fight against HIV," according to a June 25, 2025 headline in The New Yorker. But Gilead didn't stop innovating in the lab.

What makes this innovation even more impactful is the trial model for how it was developed-with intention, inclusion, real-world relevance and a landmark level of collaboration between a drug developer and the communities it serves.

Innovation has also fueled the groundbreaking access plan Gilead began developing two years ahead of any trial results. Gilead is taking unprecedented actions with urgency to plan for access to HIV medicine globally-particularly in countries where the need is greatest. Those steps include signing voluntary licensing agreements with six generic manufacturers that will provide access across 120 high-incidence, resource-limited countries, which are primarily low- and lower-middle-income countries, before any regulatory approvals were in place-marking the earliest and broadest licensing strategy ever for an HIV prevention medicine. Additionally, Gilead has launched at-risk manufacturing to provide enough supply for approximately 2 million individuals ahead of generic entry and are pursuing accelerated regulatory pathways to help bring Yeztugo to the people who need it, as quickly and affordably as possible, in regions around the world.

Twice-yearly Yeztugo represents a breakthrough in PrEP innovation-with innovation extending from scientific discovery through clinical trials to regulatory scope and global access. Yeztugo sets a new standard not just for first-in-class science, but for how to reach global public health impact.

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Please provide appropriate references (PubMed, Abstract, Website) *

The New England Journal of Medicine: Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women: https://pubmed.ncbi.nlm.nih.gov/39046157/

The New England Journal of Medicine: Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons: https://pubmed.ncbi.nlm.nih.gov/39602624/

Science: 2024 Breakthrough of the Year: https://www.science.org/content/article/breakthrough-2024

Clinical Infectious Diseases: Lenacapavir for HIV Prevention: A Commitment to Equitable Access and Partnership by Gilead Sciences: https://pubmed.ncbi.nlm.nih.gov/40202860/

Gilead press release: Yeztugo® (Lenacapavir) Is Now the First and Only FDA-Approved HIV Prevention Option Offering 6 Months of Protection: https://www.gilead.com/news/news-details/2025/yeztugo-lenacapavir-is-now-the-first-and-only-fda-approved-hiv-prevention-option-offering-6-months-of-protection

Gilead company statement: European Medicines Agency Validates Gilead's Marketing Authorization Application and EU-Medicines for All Application for Twice-Yearly Lenacapavir for HIV Prevention: https://www.gilead.com/news/news-details/2025/european-medicines-agency-validates-gileads-marketing-authorization-application-and-eu-medicines-for-all-application-for-twice-yearly-lenacapavir-for-hiv-prevention

The New Yorker: The Drug That Could Revolutionize the Fight Against HIV: https://www.newyorker.com/news/the-lede/the-drug-that-could-revolutionize-the-fight-against-hiv

An Open Letter from Daniel O'Day, Chairman & CEO, Gilead Sciences: https://www.gilead.com/stories/an-open-letter-from-daniel-oday-chairman-and-ceo

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