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Gilead Announces First Global Regulatory Approval of Sunlenca® (Lenacapavir), the Only Twice-Yearly HIV Treatment Option

– European Commission Grants Marketing Authorization for Sunlenca, Helping to Address a Critical Unmet Clinical Need for People with Multi-Drug-Resistant HIV Who Have Very Limited Treatment Choices –

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the European Commission (EC) has granted Marketing Authorization for Sunlenca® (lenacapavir) injection and tablets for the treatment of HIV infection, in combination with other antiretroviral(s), in adults with multi-drug resistant HIV infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen. Lenacapavir is a first-in-class capsid inhibitor with a multi-stage mechanism of action and has no known cross resistance to other existing drug classes, offering a new, every six-month treatment option for people with HIV whose virus no longer effectively responds to their current therapy.

“Lenacapavir helps to fill a critical unmet need for people with complex prior treatment histories and offers physicians a long-awaited twice-yearly option for these patients who are at greater risk of progressing to AIDS,” said Jean-Michel Molina, MD, Université Paris Cité, Professor of Infectious Diseases and Head of the Infectious Diseases Department at the Saint-Louis and Lariboisière Hospitals. “In the CAPELLA study, lenacapavir, in combination with other antiretroviral therapies, demonstrated sustained rates of virologic suppression and clinically meaningful CD4+ T-cell recovery in people with multi-drug resistant HIV. Lenacapavir provides an innovative long-acting HIV therapy option with the potential to transform the clinical landscape.”

The Marketing Authorization Application (MAA) for lenacapavir is supported by data from the Phase 2/3 CAPELLA study, which evaluated lenacapavir in combination with an optimized background regimen in people with multi-drug resistant HIV who are heavily treatment-experienced. In this patient population with significant unmet medical need, 83% (n=30/36) of participants receiving lenacapavir in addition to an optimized background regimen achieved an undetectable viral load (<50 copies/mL) at [Week 52](#). Additionally, CAPELLA participants achieved a mean increase in CD4 count of 83 cells/μL.

“After more than three decades of driving advancements in HIV treatment and prevention, Gilead scientists have now delivered an innovative new option for long-acting care,” said Daniel O’Day, Chairman and Chief Executive Officer, Gilead Sciences. “Lenacapavir is a unique and potent medicine with the potential for flexible dosing options. Following today’s approval, it will now be the only twice-yearly treatment for people who struggle with multi-drug resistant HIV. Our goal is to deliver multiple long-acting options in the future, in the belief that this will make a fundamental difference in the journey to end the HIV epidemic.”

Despite the significant advances in ARV therapy, there remain numerous critical and pressing unmet needs for people with HIV. This is particularly true for people with HIV who are heavily treatment-experienced with limited therapy options and are unable to maintain virologic suppression due to resistance or challenges adhering to a complex regimen. This type of complexity further increases the chance of suboptimal adherence and treatment failure, underscoring the need for a new treatment option that is active against resistant variants of the virus with a novel mechanism of action.

Sunlenca is indicated in the European Union for the treatment of adults with multi-drug resistant HIV infection in combination with other antiretroviral(s), for whom it is otherwise not possible to construct a suppressive anti-viral regimen. Lenacapavir tablets are approved for oral loading prior to administration of long-acting lenacapavir injection. The marketing authorization applies to all 27 member states of the European Union, as well as Norway, Iceland and Liechtenstein.

The European Marketing Authorization is the latest milestone in the review of lenacapavir by a major regulatory authority. In July, the U.S. Food & Drug Administration (FDA) [accepted for review](#) the New Drug Application (NDA) resubmission for investigational lenacapavir. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date of December 27, 2022. Additional regulatory filings and decisions by regulatory authorities are anticipated to continue throughout 2022.

For important safety information for Sunlenca, including dosing and method of administration, special warnings, drug interactions and adverse drug reactions, please see the Summary of Product Characteristics (SmPC) for Sunlenca, available from the European Medicines Agency website at www.ema.europa.eu.

There is currently no cure for HIV or AIDS.

About Sunlenca®

Sunlenca is a first-in-class, long-acting HIV capsid inhibitor approved in the European Union for the treatment of HIV infection, in combination with other antiretroviral(s), in people with multi-drug resistant HIV who are heavily-treatment experienced. Sunlenca's multi-stage mechanism of action is distinguishable from other currently approved classes of antiviral agents and 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 was no longer effectively responding to therapy. While most antivirals act on just one stage of viral replication, Sunlenca is designed to inhibit HIV at multiple stages of its lifecycle and has no known cross resistance to other existing drug classes. Sunlenca is the only HIV treatment option administered twice-yearly.

About CAPELLA (NCT04150068)

CAPELLA is a Phase 2/3, double-blinded, placebo-controlled global multicenter study designed to evaluate the antiviral activity of lenacapavir administered every six months as a subcutaneous injection in heavily treatment-experienced people with multi-drug resistant HIV-1 infection. CAPELLA includes men and women with HIV-1 and is being conducted at research centers in North America, Europe and Asia.

In CAPELLA, 36 participants with multi-class HIV-1 drug resistance and a detectable viral load while on a failing regimen were randomly allocated to receive oral lenacapavir or placebo in a 2:1 ratio for 14 days, in addition to continuing their failing regimen (functional monotherapy). An additional 36 participants were enrolled in a separate treatment cohort. Both cohorts are part of the ongoing maintenance period of the study evaluating the safety and efficacy of subcutaneous lenacapavir administered every six months in combination with an optimized background regimen. The primary endpoint was the proportion of participants randomly allocated to receive lenacapavir or placebo for 14 days, in addition to continuing their failing regimen, achieving ≥ 0.5 log₁₀ copies/mL reduction from baseline in HIV-1 RNA at the end of the functional monotherapy period.

Following the 14-day functional monotherapy period, participants randomly allocated to receive lenacapavir or placebo, in addition to continuing their failing regimen, started open-label lenacapavir and an optimized background regimen, while those enrolled in a separate treatment cohort received open-label lenacapavir and an optimized background regimen on Day 1. This ongoing maintenance period is evaluating the additional study endpoints of safety and efficacy of subcutaneous

lenacapavir administered every six months in combination with an optimized background regimen.

The New England Journal of Medicine published the primary outcome results of the CAPELLA study in its May 11, 2022 issue - [Capsid Inhibition with Lenacapavir in Multidrug-Resistant HIV-1 Infection](#). For further information, please see <https://clinicaltrials.gov/ct2/show/NCT04150068>.

About Gilead Sciences

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.