New Clinical Data Support the Sustained Efficacy of Long-acting Lenacapavir, Gilead’s Investigational HIV-1 Capsid Inhibitor

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— One-Year Data From the CAPELLA and CALIBRATE Trials Show Lenacapavir Led to High Rates of Virologic Suppression in Heavily Treatment-Experienced People Living with Multi-Drug Resistant HIV and Treatment-Naive People Living with HIV –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Feb. 16, 2022-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced new one-year results from the ongoing Phase 2/3 CAPELLA trial evaluating lenacapavir, the company’s investigational, long-acting HIV-1 capsid inhibitor, in heavily treatment-experienced people living with multi-drug resistant HIV. The findings demonstrated that lenacapavir, administered subcutaneously every six months in combination with other antiretrovirals, achieved high rates of virologic suppression and clinically meaningful increases in CD4 counts in people living with HIV whose virus was no longer effectively responding to their current therapy. In this patient population with high unmet medical need, 83% (n=30/36) of participants receiving lenacapavir in combination with an optimized background regimen achieved an undetectable viral load (<50 copies/mL) at Week 52. The data were presented at the 29th Conference on Retroviruses and Opportunistic Infections (virtual CROI 2022).

“I am really encouraged by the results presented today showing that the positive outcomes achieved with lenacapavir can be sustained at one year of treatment, which is a remarkable achievement for this group of people living with HIV who have limited treatment options and are at a greater risk of progressing to AIDS,” said Onyema Ogbuagu, MD, FACP, Director of HIV Clinical Trials program at Yale School of Medicine. “The potential of a long-acting antiretroviral treatment option that may achieve and maintain an undetectable viral load and that is administered only twice a year would be a true advancement that could potentially transform how providers care for certain patients with the virus.”

Lenacapavir is Gilead’s potential first-in-class, investigational long-acting HIV-1 capsid inhibitor in development for the treatment and prevention of HIV-1 infection. Lenacapavir’s multi-stage mechanism of action is distinguishable from currently approved classes of antiviral agents and could provide a new avenue for the development of long-acting therapy options for people living with or at risk for HIV-1. While most antiretroviral agents act on just one stage of viral replication, lenacapavir inhibits HIV-1 at multiple stages of its lifecycle and has no known cross resistance to other existing drug classes. If approved, lenacapavir would be the only HIV-1 treatment option administered twice yearly.

“Continued scientific innovation is essential to helping end the global HIV epidemic. Gilead is committed to driving advances in HIV treatment with the goal of offering long-acting options that address the differentiated needs and preferences of a diverse range of individuals and communities impacted by this disease,” said Jared Baeten, MD, PhD, Vice President, HIV Clinical Development, Gilead Sciences. “These latest results provide further evidence of the potential for lenacapavir, as a breakthrough innovation, to fulfill the needs of heavily treatment-experienced people living with multi-drug resistant HIV, irrespective of their prior treatment history.”

In addition to high rates of viral suppression, participants in CAPELLA achieved a mean increase in CD4 count of 83 cells/µL. Data previously presented at virtual CROI 2021, showed that the CAPELLA trial achieved its primary endpoint by demonstrating that a significantly higher proportion of participants randomly allocated to receive lenacapavir (n=24) achieved a clinically meaningful viral load reduction of at least 0.5 log_{10} copies/mL from baseline compared with those randomly allocated to receive placebo (n=12) during the 14-day functional monotherapy period (88% vs. 17%, p<0.0001). Those who received lenacapavir achieved a statistically significant greater mean decrease in viral load than those who received placebo during the functional monotherapy period (-1.93 log_{10} copies/mL vs. -0.29 log_{10} copies/mL, p<0.0001).

Lenacapavir was generally well tolerated in CAPELLA, with one adverse event (AE) leading to study drug discontinuation at Week 52 and no serious adverse events related to lenacapavir. The most common adverse events observed to date in the CAPELLA study were injection site reactions (63%), which were mostly mild or moderate in severity. The most common adverse events, excluding injection site reactions, were nausea and diarrhea (13% each) and COVID-19 (11%).

Gilead presented additional lenacapavir clinical data from the Phase 2 CALIBRATE trial, an ongoing, open-label, active-controlled trial in treatment-naive people with HIV-1 infection. The trial showed lenacapavir, given subcutaneously in combination with oral daily emtricitabine/tenofovir alafenamide (F/TAF) in the first 6 months, followed by combination with either oral daily tenofovir alafenamide (TAF) or bictegravir (BIC), or given orally in combination with emtricitabine/tenofovir alafenamide (F/TAF), achieved high rates of viral suppression by Week 54. Specifically, in the subcutaneous lenacapavir + TAF arm, 90% achieved an undetectable viral load (<50 copies/mL). In the subcutaneous lenacapavir + BIC arm, 85% achieved an undetectable viral load. In the oral lenacapavir + F/TAF arm, 85% achieved an undetectable viral load. The data were presented at virtual CROI 2022.

These results support the ongoing evaluation and further development of lenacapavir in combination with other long-acting partner agents for the treatment of HIV-1 infection and support Gilead’s long-acting oral and injectable development program.

Lenacapavir is an investigational compound and is not approved by any regulatory authority for any use and its safety and efficacy are not established. There is no cure for HIV or AIDS.

About CAPELLA (NCT04150068)

CAPELLA is a Phase 2/3, double-blinded, placebo-controlled global multicenter study designed to evaluate the antiviral activity of Gilead’s investigational, long-acting HIV-1 capsid inhibitor 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 living 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 log_{10} 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 of the study is evaluating the additional trial endpoints of safety and efficacy of subcutaneous lenacapavir administered every six months in combination with an optimized background regimen.

For further information, please see https://clinicaltrials.gov/ct2/show/NCT04150068.

About CALIBRATE (NCT04143594)
CALIBRATE is an ongoing, phase 2, open-label, active-controlled study in treatment-naïve people with HIV-1 infection designed to evaluate the efficacy and safety profile of lenacapavir-containing regimens. CALIBRATE includes men and women living with HIV-1 and is being conducted at research centers in North America, Puerto Rico and the Dominican Republic.

In CALIBRATE, 182 participants were randomly allocated (2:2:2:1) into one of the four treatment groups. The first and second groups received subcutaneous lenacapavir every 26 weeks following an oral lead-in period together with daily F/TAF; at Week 28, those achieving HIV-1 RNA viral load <50 copies/mL switched their F/TAF to oral daily TAF or BIC, while continuing lenacapavir. The third group received oral daily lenacapavir with F/TAF. The fourth group received oral daily B/F/TAF. The primary endpoint of the study is the proportion of participants achieving a viral load of <50 c/mL at Week 54.

For further information, please see https://clinicaltrials.gov/ct2/show/NCT04143594.

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.

For more than 30 years, Gilead has been a leading innovator in the field of HIV, driving advances in treatment, prevention and cure research. Gilead researchers have developed 11 HIV medications, including the first single-tablet regimen to treat HIV and the first antiretroviral for pre-exposure prophylaxis (PrEP) to reduce the risk of acquiring HIV infection. These advances in medical research have helped to transform HIV into a preventable, chronic condition for millions of people.

Gilead is committed to continued scientific innovation to provide solutions for the evolving needs of people affected by HIV around the world. Through partnerships and collaborations, the company also aims to improve education, expand access and address barriers to care, with the goal of ending the HIV epidemic for everyone, everywhere.

Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.

Forward-Looking Statements
This statement includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including Gilead’s ability to initiate, progress and complete clinical trials in the anticipated timelines or at all, the risk that FDA may not remove clinical holds currently in place on clinical trials and the possibility of unfavorable results from ongoing and additional clinical trials, including those involving lenacapavir; the possibility that Gilead may make a strategic decision to discontinue development of lenacapavir and as a result, lenacapavir may never be successfully commercialized; Gilead’s ability to receive regulatory approvals in a timely manner or at all, including approvals of lenacapavir, and the risk that any such approvals, if granted, may have significant limitations on its use; and any assumptions underlying any of the foregoing. These and other risks, uncertainties and factors are described in detail in Gilead’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, as filed with the U.S. Securities and Exchange Commission. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The reader is cautioned that any such forward-looking statements are not guarantees of future performance and is cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation and disclaims any intent to update any such forward-looking statements.

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For more information about Gilead, please visit the company’s website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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