June 24, 2022

Investigational Lenacapavir Receives Positive CHMP Opinion for People With Multi-Drug Resistant HIV

– Recommendation is Based on Week 26 Data from the CAPELLA Trial Showing Twice-Yearly Lenacapavir Achieved High Rates of Virologic Suppression in Heavily Treatment-Experienced People with HIV –

– If Authorized, Lenacapavir Could Offer a New, Every Six-Month Treatment Option for People with Limited Treatment Choices –

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion for investigational lenacapavir for the treatment of HIV-1 infection, in combination with other antiretroviral(s), in adults with multi-drug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen.

The CHMP positive opinion is a scientific recommendation to the European Commission (EC) to grant marketing authorization in Europe and will be reviewed by the EC, which has the authority to authorize medicines in the 27 Member States of the European Union, as well as Norway, Iceland and Liechtenstein. The final European Commission decision is expected later this year.

“Treatment options are extremely limited for people living with HIV whose virus is no longer effectively controlled by their current regimen. We are encouraged by this CHMP positive opinion for lenacapavir, as it is an important step toward a potential new treatment option for individuals with multi-drug resistant HIV,” said Jared Baeten, MD, PhD, Vice President, HIV Clinical Development, Gilead Sciences. “We look forward to the final decision by the European Commission and the potential for lenacapavir to help fill a critical unmet need for persons living with HIV with complex prior treatment histories.”

The positive opinion is supported by data from the Phase 2/3 CAPELLA trial, a double-blinded, placebo-controlled global multicenter study designed to evaluate the antiviral activity of lenacapavir administered every six months as a subcutaneous

injection, in combination with other antiretroviral(s), in heavily treatment-experienced people with multi-drug resistant HIV-1 infection. In this patient population of high unmet medical need, 81% (n=29/36) of participants receiving lenacapavir in addition to an optimized background regimen achieved an undetectable viral load (<50 copies/mL) at Week 26. Additionally, CAPELLA participants achieved a mean increase in CD4 count of 81 cells/µL. The New England Journal of Medicine published the primary outcome results of the CAPELLA trial in its May 11, 2022 issue - Capsid Inhibition with Lenacapavir in Multidrug-Resistant HIV-1 Infection. Through Week 26, lenacapavir was generally well tolerated, with no serious adverse events related to lenacapavir as determined by the study investigator. The most common adverse events observed in the trial were injection-site reactions.

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 Lenacapavir

Lenacapavir is Gilead's potential first-in-class, investigational long-acting HIV-1 capsid inhibitor in development for the treatment of HIV-1 infection. The safety, efficacy and dosing of Gilead's investigational, long-acting HIV-1 capsid inhibitor lenacapavir are being evaluated in multiple ongoing clinical studies. Lenacapavir's multi-stage mechanism of action is distinguishable from currently approved classes of antiviral agents and is designed to provide a new avenue for the development of long-acting therapy options for people with or at risk for HIV-1. While most antivirals act on just one stage of viral replication, lenacapavir is designed to inhibit HIV-1 at multiple stages of its lifecycle and has no known cross resistance to other existing drug classes. If authorized, lenacapavir would be the only HIV-1 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 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 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.