GILEAD AND MERCK INITIATE PHASE 2 STUDY EVALUATING AN ORAL WEEKLY COMBINATION REGIMEN OF INVESTIGATIONAL LENACAPAVIR AND INVESTIGATIONAL ISLATRAVIR FOR HIV-1 TREATMENT IN VIROLOGICALLY SUPPRESSED ADULTS

– This Clinical Study is the First from Merck and Gilead's Collaboration to Develop Potential Long-Acting HIV Treatment Options –

FOSTER CITY, Calif. & KENILWORTH, N.J.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) and Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced the start of a Phase 2 clinical study evaluating an investigational once-weekly oral combination treatment regimen of islatravir and lenacapavir in people living with HIV who are virologically suppressed on antiretroviral therapy.

"Partnerships and collaborations are critical to continuing the tremendous progress that has been made toward ending the HIV epidemic," said Jared Baeten, MD, PhD, Vice President, HIV Clinical Development, Gilead Sciences. "This innovative research collaboration builds on the efforts of both companies to help make the end of the epidemic a reality through continued scientific advances in HIV. Initiating the trial represents an important step forward toward our goal of offering long-acting options that can help address the differentiated needs and preferences of the diverse range of people living with HIV."

Through the collaboration between Merck and Gilead, announced in March 2021, the companies seek to build on their legacies of transforming HIV care by focusing on long-acting therapies, which may represent a meaningful innovation in HIV drug development.

"The initiation of this study is key to further understanding the potential of islatravir and lenacapavir in combination for the treatment of HIV-1, and demonstrates Merck and Gilead's shared commitment to address the unmet needs of people living with HIV and to contribute to global efforts to end the pandemic," said Dr. Joan Butterton, vice president, global clinical development, infectious diseases, Merck Research Laboratories.

Both islatravir and lenacapavir have long half-lives and have demonstrated activity at low dosages in independent clinical studies, which support the development as an investigational combination regimen with long-acting formulations, both oral and injectable. While daily, single tablet oral regimens are available for people living with HIV, oral or injectable regimen options that allow for less frequent dosing have the potential to address preference considerations, as well as issues associated with stigma, adherence, and privacy.

The Phase 2 study is designed to evaluate the safety and antiviral effect of an oral weekly regimen of Merck's investigational nucleoside reverse transcriptase translocation inhibitor, islatravir, in combination with Gilead's investigational capsid inhibitor, lenacapavir. The primary endpoint is the proportion of study participants with HIV-1 RNA viral load ≥ 50 c/mL at Week 24.

Lenacapavir and islatravir, alone and in combination, are investigational and not approved anywhere globally. Their safety and efficacy have not yet been established.

There is currently no cure for HIV or AIDS.

About NCT05052996

This Phase 2, open-label, active-controlled, multicenter study is designed to evaluate the safety and antiviral effect of an oral weekly regimen of islatravir in combination with lenacapavir in virologically suppressed people with HIV. Participants age 18 years and older will be enrolled in this study, which is being conducted at 25 sites in the United States.

In the trial, 75 participants who meet all eligibility criteria will be randomly allocated in a 2:1 ratio to receive oral weekly islatravir (20 mg) administered with oral lenacapavir (300 mg) on day 8 following a loading dose of islatravir (40 mg) and lenacapavir (600 mg) on days 1 and 2 or oral daily B/F/TAF (bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg tablets). Participants will receive study drugs for 48 weeks.

Following completion of the Week 48 visit, participants in Treatment Group 1 will continue to receive an oral weekly regimen of islatravir in combination with oral lenacapavir and be evaluated every 12 weeks. Participants in Treatment Group 2 will switch from daily oral B/F/TAF tablets to an oral weekly regimen of islatravir in combination with oral lenacapavir (starting with the loading doses over 2 days) and continue the study with visits every 12 weeks thereafter.

About Lenacapavir
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 is designed to provide a new avenue for the development of long-acting therapy options for people living 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.

About Islatravir (MK-8591)
Islatravir (MK-8591) is Merck's investigational nucleoside reverse transcriptase translocation inhibitor under evaluation in more than 10 clinical trials. For treatment, islatravir is being evaluated in combination with other antiretrovirals, including the ILLUMINATE clinical trials program for a once-daily regimen. In the IMPOWER clinical trials, islatravir is also being studied for pre-exposure prophylaxis (PrEP) of HIV-1 infection as a single agent across a variety of formulations, including an oral once-monthly regimen. An overview of the islatravir treatment and prevention development program is available here. In 2012, Merck licensed islatravir (4'-ethynyl-2-fluoro-2'-deoxyadenosine or EFdA) from the Yamasa Corporation based in Choshi, Japan.