NEWS RELEASE

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

10/26/2021

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., October 26, 2021 – 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.

For further information, please see: **https://clinicaltrials.gov/ct2/show/NCT05052996**

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.

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.

About Merck

For more than 130 years, Merck, known as MSD outside the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. For more information, visit **www.merck.com** and connect with us on **Twitter**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

For more than 35 years, Merck has been committed to scientific research and discovery (R&D) in HIV. Today, we are developing a series of antiviral options designed to help people manage HIV and protect people from HIV, with the goal of reducing the growing burden of infection worldwide. We remain committed to working hand-in-hand with our partners in the global HIV community to address the complex challenges that hinder continued progress toward ending the epidemic.

Gilead Forward-Looking Statements

This press release 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 the risk that Gilead may not realize any anticipated benefits from this collaboration; difficulties or unanticipated expenses in connection with the collaboration and the potential effects on Gilead's revenues and earnings; the ability of the companies to initiate and complete clinical trials in the anticipated timelines or at all, including those involving lenacapavir, the combinations of lenacapavir and islatravir and other investigational oral integrase inhibitors; the possibility of unfavorable results from ongoing and additional clinical trials, including those involving lenacapavir, the combinations of lenacapavir and islatravir and other investigational oral integrase inhibitors; the ability of the companies to successfully co-develop and co-commercialize long-acting HIV treatments; uncertainties relating to regulatory applications and related filing and approval timelines, including the risk that regulatory authorities may not approve such applications in the anticipated timelines or at all, and any marketing approvals, if granted, may have significant limitations on its use; the possibility that the companies may make a strategic decision to terminate this collaboration; the possibility that Gilead may make a strategic decision to discontinue development of lenacapavir and as a result, lenacapavir may never be successfully commercialized; 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 June 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.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of the global outbreak of novel coronavirus disease (COVID-19); the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2020 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

###

Merck Investor Contact:
Peter Dannenbaum
(908) 740-1037

Merck Investor Contact:
Sienna Choi
(908) 873-4311

Gilead Investor Contact:
Jacquie Ross
(650) 358-1054

Gilead Media Contact:
Brian Plummer
(202) 309-5207