



Gilead and Merck Announce Agreement to Jointly Develop and Commercialize Long-Acting, Investigational Treatment Combinations of Lenacapavir and Islatravir in HIV

March 15, 2021

– Collaboration to Focus on Oral and Injectable Formulations of Lenacapavir and Islatravir –

– Agreement Brings Together Potentially Complementary Medicines in Late-Stage Development with the Goal to Provide Innovative, Long-Acting Treatments in HIV –

FOSTER CITY, Calif. & KENILWORTH, N.J.--(BUSINESS WIRE)--Mar. 15, 2021-- Gilead Sciences, Inc. (Nasdaq: GILD) and Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that they have entered into an agreement to co-develop and co-commercialize long-acting treatments in HIV that combine Gilead's investigational capsid inhibitor, lenacapavir, and Merck's investigational nucleoside reverse transcriptase translocation inhibitor, islatravir, into a two-drug regimen with the potential to provide new, meaningful treatment options for people living with HIV.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20210315005226/en/>

Islatravir and lenacapavir are both potentially first-in-class medicines in late-stage clinical trials, with significant clinical data generated to date. Both medicines have long half-lives and have demonstrated activity at low dosages in clinical studies, which support development as an investigational combination regimen with long-acting formulations, both oral and injectable.

The first clinical studies of the oral combination are expected to begin in the second half of 2021. Under the terms of the agreement, Gilead and Merck will work as partners, sharing operational responsibilities, as well as development, commercialization and marketing costs, and any future revenues.

Merck and Gilead 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. While daily, single tablet regimens are available for people living with HIV, options that would allow for less frequent, oral dosing or infrequent injections rather than daily dosing have the potential to address preference considerations, as well as issues associated with adherence and privacy.

As the field of HIV treatment evolves, long-acting therapies may provide additional options for people living with HIV and their physicians that will help continue to put the needs of individuals at the center of their own care.

"At Merck, we are resolute in our commitment to advancing the care of people living with HIV as part of our mission to save and improve lives," said Kenneth C. Frazier, Chairman and Chief Executive Officer, Merck. "This collaboration with Gilead brings together two companies dedicated to the fight against HIV to develop potential new long-acting treatment options, and is an important step forward in our strategy to harness the full potential of islatravir for the treatment of HIV."

"Through this agreement with Merck, Gilead is reinforcing its long-term role in transforming HIV care," said Daniel O'Day, Chairman and Chief Executive Officer, Gilead Sciences. "Our work in HIV over the past decades has been shaped by listening to people living with HIV and the physicians who treat them. Now we are taking the same approach with long-acting therapies, combining the most advanced science from both companies to accelerate progress."

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

Terms of the Collaboration

Under the terms of the agreement, Gilead and Merck will co-develop and co-commercialize long-acting products to treat people living with HIV that combine Gilead's proprietary investigational capsid inhibitor, lenacapavir, and Merck's proprietary investigational nucleoside reverse transcriptase translocation inhibitor, islatravir. The collaboration will initially focus on long-acting oral formulations and long-acting injectable formulations of these combination products, with other formulations potentially added to the collaboration as mutually agreed.

Across the oral and injectable formulation programs, Gilead and Merck will share global development and commercialization costs 60%/40%, respectively. For long-acting oral products, Gilead will lead commercialization in the U.S. and Merck will lead commercialization in the EU and rest of the world. For long-acting injectable products, Merck will lead commercialization in the U.S. and Gilead will lead commercialization in the EU and rest of the world.

Gilead and Merck will co-promote in the U.S. and other certain major markets. Merck and Gilead will share global product revenues equally until product revenues surpass certain pre-agreed per formulation revenue tiers. Upon passing \$2 billion a year in net product sales for the oral combination, the revenue split will adjust to 65% Gilead and 35% Merck for any revenues above the threshold. Upon passing \$3.5 billion a year in net product sales for the injectable combination, the revenue split will adjust to 65% Gilead and 35% Merck for any revenues above the threshold.

Beyond the potential combinations of lenacapavir and islatravir, Gilead will have the option to license certain of Merck's investigational oral integrase inhibitors to develop in combination with lenacapavir. Reciprocally, Merck will have the option to license certain of Gilead's investigational oral integrase inhibitors to develop in combination with islatravir. Each company may exercise its option for an investigational oral integrase inhibitor of the other company following completion of the first Phase 1 clinical trial of that integrase inhibitor. Upon exercise of an option, the companies will split development cost and revenues, unless the non-exercising company decides to opt-out. Both companies currently have oral once-weekly integrase inhibitors in preclinical development.

Cowen & Company LLC is acting as financial advisor to Gilead. Hogan Lovells and White & Case, LLP are serving as legal counsel to Gilead. Morgan,

Lewis & Bockius and Gibson Dunn are serving as legal counsel to Merck.

About Islatravir (MK-8591)

Islatravir (formerly MK-8591) is Merck's investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) that exhibits both translocation inhibition (which prevents nucleotide binding and incorporation to the DNA chain, resulting in immediate chain termination) and delayed chain termination (which prevents nucleotide incorporation even in the event of translocation). Islatravir is currently being evaluated for the treatment of HIV-1 infection in combination with other antiretrovirals, including the ILLUMINATE clinical trials program for oral, once-daily treatment. Islatravir is also being studied for preexposure prophylaxis (PrEP) of HIV-1 infection as a single agent across a variety of formulations, including the IMPOWER clinical trials evaluating an oral once-monthly regimen. In 2012, Merck licensed islatravir (4'-ethynyl-2'-deoxyadenosine or EFdA) from the Yamasa Corporation based in Choshi, Japan.

About Lenacapavir

Lenacapavir is a novel investigational capsid inhibitor that interrupts the activity of HIV capsid, a protein that surrounds and protects the virus' genetic material and essential enzymes. In *in vitro* studies, lenacapavir interrupts multiple distinct stages of the viral lifecycle, potentially preventing the virus from becoming infectious and gaining access to uninfected cells.

The safety, efficacy and dosing of lenacapavir are being evaluated in multiple ongoing clinical studies. Data presented at AIDS 2020 from the ongoing Phase 1 study support subcutaneous every six-month administration of lenacapavir for both HIV treatment and prevention studies. During IDWeek 2020, the company announced it would be evaluating the use of lenacapavir among cisgender women as an injectable PrEP option administered every six months. An additional lenacapavir for PrEP study in men who have sex with men and persons of trans experience is planned. Both studies are expected to begin in 2021.

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. For more information about Gilead, please visit the company's website at www.gilead.com.

For more than 30 years, Gilead has been a leading innovator in the field of HIV, driving advances in treatment, prevention, testing and linkage to care, and cure research. Today, millions of people living with HIV globally receive antiretroviral therapy provided by Gilead or one of the company's manufacturing partners.

About Merck

For more than 130 years, Merck, known as MSD outside of 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 in HIV, and we continue to be driven by the conviction that more medical advances are still to come. Our focus is on pursuing research that addresses unmet medical needs and helps people living with HIV and their communities. 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 involving the combinations of lenacapavir and islatravir and other investigational oral integrase inhibitors in the anticipated timelines or at all; the possibility of unfavorable results from ongoing and additional clinical trials, including other Gilead trials involving lenacapavir; 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; and the possibility that the companies may make a strategic decision to terminate this collaboration. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation 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).

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Gilead

Marni Kottle, Media
(650) 522-5388

Jacquie Ross, Investors
(650) 358-1054

Merck

Peter Dannenbaum, Investors
(908) 740-1037

Ian McConnell, Media
(973) 901-5722

Source: Gilead Sciences, Inc.