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GILEAD AND MERCK ANNOUNCE POSITIVE TOPLINE RESULTS FROM TWO PHASE 3 STUDIES EVALUATING ISLATRAVIR/LENACAPAVIR, AN ORAL ONCE-WEEKLY HIV TREATMENT

- Novel Investigational Combination Pairs Merck’s Islatravir, a Next-Generation Nucleoside Analog with Multiple Mechanisms of Action, including Translocation Inhibition, with Gilead’s Lenacapavir, a First-in-Class Capsid Inhibitor that Disrupts HIV at Multiple Stages of its Lifecycle –*
- Islatravir/Lenacapavir has the Potential to be the First Approved Long-Acting Oral HIV Treatment Taken Once-Weekly–*

Foster City, Calif. & Rahway, N.J., June 8, 2026 – FOSTER CITY, Calif., & RAHWAY, N.J.-- (BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) and Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced that the primary efficacy endpoint at Week 48 was met in both the Phase 3 ISLEND-1 and ISLEND-2 trials with the investigational oral once-weekly single-tablet HIV treatment regimen of islatravir/lenacapavir. The ISLEND trials are evaluating the efficacy and safety of islatravir 2mg/lenacapavir 300mg (ISL/LEN) in people with HIV who are virologically suppressed switched from BIKTARVY® (bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg tablets, B/F/TAF) (ISLEND-1) or daily standard of care antiretroviral regimens (ISLEND-2). The safety profile of ISL/LEN was generally comparable to the other comparator regimens studied in the ISLEND trials, and no new safety concerns were identified. Gilead and Merck plan to file the Phase 3 data from the ISLEND trials with regulatory authorities globally and submit the detailed findings for presentation at a future scientific congress.

“Long-acting oral therapies represent a new wave of transformational innovation in HIV drug development, with the potential to reshape the landscape of care,” said Jared Baeten, MD, PhD, Senior Vice President, Clinical Development, Virology Therapeutic Area Head, Gilead Sciences. “Innovative oral HIV treatment options that allow for less frequent dosing may make a meaningful difference in the lives of people living with the virus, potentially offering more flexibility and discretion”.

The primary efficacy endpoint of ISLEND-1 and ISLEND-2 was the percentage of participants with HIV-1 RNA levels ≥ 50 copies/mL at Week 48, defined by the FDA snapshot algorithm. In the double-blind ISLEND-1 trial, the once-weekly, single-tablet regimen of ISL/LEN was found to be statistically non-inferior to Biktarvy. In the open-label ISLEND-2 trial, ISL/LEN was found to be statistically non-inferior to standard of care daily oral antiretroviral therapy regimens. The safety profile of ISL/LEN was generally comparable to BIKTARVY in ISLEND-1 and to standard of care antiretroviral regimens in ISLEND-2.

“These results underscore the shared focus and commitment that we and our collaborators at Gilead have on continuing research to help people living with HIV. By advancing this investigational novel once-weekly oral regimen of islatravir and lenacapavir, we aim to bring forward a new long-acting oral option that, if approved, would represent the first of its kind with less frequent dosing and further expand options for people living with HIV,” said Dr. Eliav Barr, senior vice president head of global clinical development and chief medical officer, Merck Research Laboratories.

The combination of islatravir and lenacapavir targets multiple stages of HIV-1 replication, potentially offering people with virologically suppressed HIV a novel, long-acting oral single-tablet regimen. The potency and pharmacokinetic profiles of islatravir and lenacapavir enable long-acting dosing as a once-weekly tablet for HIV treatment, if approved.

Islatravir and lenacapavir in combination are investigational and not approved for use.

There is currently no cure for HIV or AIDS.

About ISLEND-1

ISLEND-1 ([NCT06630286](#)) is a Gilead-sponsored, multicenter Phase 3 randomized, double-blind, active-controlled trial designed to evaluate the safety and efficacy of switching to a once-weekly tablet of islatravir/lenacapavir (ISL/LEN) versus continuing treatment with BIKTARVY (bictegravir/emtricitabine/tenofovir alafenamide) in people with virologically suppressed HIV (HIV-1 RNA levels < 50 copies/mL) on BIKTARVY for ≥ 6 months prior to screening. Participants were randomized 1:1 to receive an initial dose of ISL/LEN followed by ISL/LEN once-weekly Day 8 to Week 96 plus BIKTARVY placebo daily, or BIKTARVY daily plus an initial placebo dose of ISL/LEN followed by placebo once-weekly ISL/LEN from Day 8 to Week 96. The primary endpoint was the proportion of participants with HIV-1 RNA ≥ 50 copies/mL at Week 48, as determined by the US FDA-defined snapshot algorithm. Key secondary endpoints included the proportion of participants with HIV-1 RNA ≥ 50 copies/mL at Week 96, as determined by the US FDA-defined snapshot algorithm; the proportion of participants with virologic suppression (HIV viral load < 50 copies/mL per US FDA Snapshot) at Week 48 and Week 96; change from baseline in CD4 cell count at Week 48 and Week 96; and the proportion of participants treated with ISL/LEN who discontinued treatment due to treatment-emergent adverse events.

About ISLEND-2

ISLEND-2 ([NCT06630299](#)) is a Gilead-sponsored, multicenter Phase 3 randomized, open-label, active-controlled trial evaluating the safety and efficacy of switching to a once-weekly tablet of ISL/LEN versus continuation of standard of care treatment in people with virologically suppressed HIV (HIV-1 RNA levels < 50 copies/mL) on a stable standard of care antiretroviral regimen for ≥ 6 months prior to screening. A standard of care regimen included two or three antiretroviral medicines, including integrase strand transfer inhibitors (INSTI), nucleoside reverse transcriptase inhibitors (NRTIs), boosted protease inhibitors (PI) and non-nucleoside reverse transcriptase inhibitors (NNRTI). Participants either received an initial dose of ISL/LEN followed by once-weekly ISL/LEN from Day 8 to Week 96, or continued their standard of care treatment with two/three antiretroviral medicines up to Week 96. The primary endpoint is the proportion of

participants with HIV-1 RNA $\geq$ 50 copies/mL at Week 48 by FDA-defined Snapshot Algorithm. Key secondary endpoints included the proportion of participants with HIV-1 RNA $\geq$ 50 copies/mL at Week 96, as determined by the US FDA-defined snapshot algorithm; the proportion of participants with virologic suppression (HIV viral load $<$ 50 copies/mL per US FDA Snapshot) at Week 48 and Week 96; change from baseline in CD4 cell count at Week 48 and Week 96; and the proportion of participants treated with ISL/LEN who discontinued treatment due to treatment-emergent adverse events.

About Lenacapavir

The multi-stage mechanism of action of lenacapavir is distinguishable from other approved classes of antiretroviral agents. While most antiretrovirals act on one stage of viral replication, lenacapavir is designed to inhibit HIV at multiple stages of its lifecycle and has no known exhibited cross-resistance in vitro to other existing drug classes.

Lenacapavir is being evaluated as a long-acting option in multiple ongoing and planned early and late-stage clinical studies in Gilead's HIV treatment and prevention research program. Lenacapavir is being developed as a foundation for potential future HIV therapies to offer both long-acting oral and injectable options with several dosing frequencies, in combination or as a mono agent, that help address the individual needs and preferences of people and communities affected by HIV.

For an overview of Gilead's HIV treatment and prevention clinical development program, please click [here](#).

About Islatravir (MK-8591)

Islatravir (MK-8591) is Merck's potent, next-generation nucleoside analog that blocks HIV-1 replication by multiple mechanisms including inhibition of reverse transcriptase translocation, resulting in immediate chain termination, and induction of structural changes in the viral DNA (delayed chain termination).

Islatravir is anchoring multiple ongoing early and late-stage clinical trials of two-drug regimens in combination with other Merck antiretrovirals for potential treatments for HIV-1. Islatravir is being studied in Phase 3 in combination with Merck's doravirine (DOR/ISL) as a once-daily pill for treatment of HIV-1 infection in adults with no prior antiviral treatment history and in Phase 2b in combination with Merck's investigational non-nucleoside reverse transcriptase inhibitor (NNRTI) ulonivirine (MK-8507) as an oral once-weekly treatment for HIV-1.

For an overview of Merck's HIV treatment and prevention clinical development program, please click [here](#).

About Gilead HIV

For almost 40 years, Gilead has been a leading innovator in the field of HIV, driving advances in treatment, prevention and cure research. Gilead researchers have developed 13 HIV [medications](#), including the first single-tablet regimen to treat HIV, the first antiretroviral for pre-exposure prophylaxis (PrEP) to help reduce new HIV infections, and the first long-acting injectable HIV prevention medication administered twice-yearly. Our advances in [medical research](#) have helped to transform HIV into a treatable, 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](#), collaborations and charitable giving, the company also aims to improve education, expand [access](#) and address barriers to care, with the goal of ending the HIV epidemic worldwide. Gilead has been repeatedly [recognized](#) as one of the top two leading philanthropic funders of HIV-related programs in a report released by Funders Concerned About AIDS.

Discover more about Gilead's [unique collaborations worldwide](#) and the work to help end the HIV epidemic.

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, COVID-19, cancer and inflammation. In 2025, Gilead announced a planned \$32 billion investment to further strengthen its U.S. footprint to power the next era of discovery, job creation and public health preparedness – while continuing to invest globally to ensure patients everywhere benefit from its scientific innovation. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, Calif.

Merck's Commitment to HIV

For 40 years, Merck has been committed to scientific research and discovery in HIV leading to scientific breakthroughs that have helped change HIV treatment. Our work has helped pioneer the development of new options across multiple drug classes to help those impacted by HIV. Today, we are developing a series of antiviral options designed to help people manage HIV and protect people from HIV. We are researching for real life and want to ensure people are not defined by HIV. Our work focuses on transformational innovations, collaborations with others in the global HIV community, and access initiatives aimed at helping to end the HIV epidemic for everyone.

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit www.merck.com and connect with us on [X \(formerly Twitter\)](#), [Facebook](#), [Instagram](#), [YouTube](#) and [LinkedIn](#).

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 Gilead's ability to initiate, progress or complete clinical trials or studies within currently anticipated timelines or at all, and the possibility of unfavorable results from ongoing and additional clinical trials or studies, including those involving lenacapavir (such as ISLEND-1 and ISLEND-2); uncertainties relating to regulatory applications and related filing and approval timelines, including potential applications for programs and/or indications currently under evaluation, such as oral once-weekly single-tablet HIV treatment regimen of islatravir/lenacapavir, and the risk that any regulatory approvals, if granted, may be subject to significant limitations on use or subject to withdrawal or other adverse actions by the applicable regulatory authority; the possibility that Gilead may make a strategic decision to discontinue development of these programs and, as a result, these programs may never be successfully commercialized for the indications currently under evaluation; 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 March 31, 2026, 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 involve risks and uncertainties 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., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, 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 candidates that the candidates 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 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 Annual Report on Form 10-K for the year ended December 31, 2025 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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For more information about Gilead, please visit the company’s website at www.gilead.com, follow Gilead on X([@Gilead Sciences](#)) and [LinkedIn](#), or [contact](#) Gilead Public Affairs.