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Investigational Once-weekly Oral HIV Treatment Regimen of Islatravir and Lenacapavir Maintained Virological Suppression in Adults With HIV Who Switched Antiretroviral Therapy

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- High Rates of Virologic Suppression Sustained at Week 48 Across ISL/LEN Treatment Groups in Both Phase 3 ISLEND Trials -

- ISL/LEN has the Potential to be the First Once-Weekly Oral HIV Treatment -

FOSTER CITY, CA, & RAHWAY, NJ, July 21, 2026 – Gilead Sciences, Inc. (Nasdaq: GILD) and Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced that the detailed outcomes from the Phase 3 ISLEND-1 and ISLEND-2 trials will be presented for the first time at the 26th International AIDS Conference ([AIDS 2026](#)). The primary endpoint results at Week 48 showed that the investigational once-weekly oral single-tablet HIV treatment regimen of islatravir 2 mg/lenacapavir 300 mg (ISL/LEN) was effective in adults living with HIV who were virologically suppressed and switched from global guideline-recommended BIKTARVY® (bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg tablets, B/F/TAF) (ISLEND-1) or other standard of care oral daily antiretroviral regimens (ISLEND-2). The safety profile of ISL/LEN was generally similar to the comparator regimens studied in the ISLEND trials, and no new safety concerns were identified. Results of both trials will be presented during late-breaking sessions at AIDS 2026 on Wednesday, July 29 and featured in the AIDS 2026 press program on Tuesday, July 21. These data will form the basis of regulatory submissions.

The ISLEND-1 ([NCT06630286](#)) and ISLEND-2 ([NCT06630299](#)) trials evaluated the safety and efficacy of the once-weekly single tablet regimen of ISL/LEN. The data provide strong evidence for the potential of ISL/LEN to be the first and only once-weekly oral HIV treatment option for adults with virologic suppression on a stable antiretroviral regimen. The investigational combination pairs Merck's islatravir, a next-generation nucleoside analog with multiple mechanisms of action including HIV-1 reverse transcriptase translocation inhibition, with Gilead's lenacapavir, a first-in-class capsid inhibitor that disrupts HIV-1 at multiple stages of its lifecycle. The potency and pharmacokinetic

promies or islatravir and lenacapavir enable dosing as a complete once-weekly tablet for HIV treatment.

Results from ISLEND-1

Week 48 results showed that the once-weekly single tablet regimen of ISL/LEN was noninferior to BIKTARVY in maintaining virologic suppression; no (0%) participants who switched to ISL/LEN had HIV-1 RNA $\geq$ 50 copies/mL at Week 48 compared to 1 (0.3%) participant who remained on BIKTARVY (as determined by the US FDA-defined snapshot algorithm).

“Once-daily, combination, single-tablet antiretroviral therapy is the cornerstone of HIV treatment today. However, the treatment landscape is evolving,” said Jürgen Rockstroh, Department of Medicine University Hospital Bonn, Germany. “Long-acting therapies provide an alternative to daily pills. The ISLEND-1 study results show the potential of ISL/LEN as the first once-weekly oral single-tablet treatment option.”

In this blinded trial, treatment-related adverse events were reported in 13.5% of participants who switched to ISL/LEN and 13.2% of participants who remained on BIKTARVY and were generally comparable between groups. In both treatment groups, the most common treatment-related adverse events reported were nausea (3%) and headache (3%). A similar incidence of serious adverse events was reported in both treatment groups (5.3% ISL/LEN; 4.6% BIKTARVY). Discontinuations of ISL/LEN or BIKTARVY due to adverse events were low (2% and 1.7%, respectively). CD4+ T-cell and lymphocyte counts were stable in both treatment groups through Week 48 and no participant discontinued due to a decrease in CD4+ T-cell or lymphocyte count. There was no clinically meaningful difference in changes in body weight between the treatment groups at Week 48.

Results from ISLEND-2

At Week 48, ISL/LEN was found to be non-inferior to daily oral standard of care HIV treatments; 0.3% of participants receiving ISL/LEN had HIV-1 RNA $\geq$ 50 copies/mL compared to 1.3% who remained on standard of care antiretroviral regimens (as determined by the US FDA-defined snapshot algorithm).

“Single tablet regimens have transformed the outlook for millions of people living with HIV,” said Amy Colson, Research Director at Community Resource Initiative and Medical Director of the Zinberg Clinic at Cambridge Health

Alliance. “Having a treatment option with once weekly dosing can expand choice to help address individual needs and preferences. The 48-week findings provide the evidence for ISL/LEN as the potential first once-weekly oral treatment option to help support long-term treatment needs and be responsive to the preferences of people living with HIV.”

In this open-label trial, treatment-related adverse events were reported in 18% of participants treated with ISL/LEN and <1% receiving standard of care antiretroviral regimens. In the ISL/LEN group, the most common treatment-related adverse events reported ($\geq 2\%$) were headache (5%), nausea (3%) and diarrhea (3%). Discontinuations of study drug due to adverse events were low (1% and <1%, respectively). CD4+ T-cell counts and lymphocyte counts were stable in both treatment groups through Week 48 and no participant discontinued due to a decrease in CD4+ T-cell or lymphocyte counts. Through Week 48, body weight remained stable in both treatment groups.

Additionally, participants who switched to once-weekly oral ISL/LEN reported higher treatment satisfaction and lower treatment burden compared with taking standard of care daily HIV treatments based on HIV Patient Perspective of Regimen Change outcomes reporting.

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 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 initial doses of ISL/LEN on Day 1 and Day 2 followed by once-weekly ISL/LEN from Day 8 to Week 96 plus placebo-to-match BIKTARVY daily, or BIKTARVY daily plus placebo-to-match initial doses of ISL/LEN on Day 1 and Day 2 and placebo-to-match once-weekly ISL/LEN from Day 8 to Week 96. The study will remain blinded until all participants complete their Week 96 visit. 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 $\geq$ 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 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 $\geq$ 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 were randomized 1:1 to receive initial doses of ISL/LEN on Day 1 and Day 2 followed by once-weekly ISL/LEN from Day 8 to Week 96 or to continue their daily oral standard of care treatment with two or 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. Patient-reported outcomes are an exploratory outcome of this open-label trial.

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 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 more than 40 years, Merck has been committed to 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 for both HIV treatment and prevention. We're inspired by the lived experiences of the HIV community as we advance research with real life in mind. Our work focuses on transformational innovations, collaborations with others in the global HIV community, and access initiatives to help end the HIV epidemic.

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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