NEWS RELEASE

Merck to Present New Data from Its Broad Oral HIV Portfolio and Pipeline at HIV Glasgow 2026

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Presentations include data on daily and investigational once-weekly oral treatments and investigational once-monthly oral HIV pre-exposure prophylaxis

New data include Phase 3 subgroup analyses and patient-reported outcomes of investigational once-weekly oral combination of islatravir/lenacapavir (ISL/LEN)

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that new data across its HIV treatment and prevention pipeline and portfolio will be presented at HIV Drug Therapy Glasgow 2026 (**HIV Glasgow 2026**), taking place Nov 8–11, 2026, in Glasgow, Scotland. Presentations will highlight Merck's strategy to expand oral options in both HIV treatment and prevention, including data on once-daily IDVYNSO® (doravirine/islatravir), the investigational once-weekly oral treatment regimens islatravir/lenacapavir (ISL/LEN) and islatravir/ulonivirine (ISL/ULO), and the investigational once-monthly oral pre-exposure prophylaxis (PrEP) alimatravir (AMI, MK-8527).

"The data being presented at HIV Glasgow reflect the breadth of our research across HIV treatment and prevention," said Dr. Luisa Stamm, associate vice president and HIV section head at Merck Research Laboratories. "Our goal is to bring forward oral options, including daily and once-weekly HIV treatment regimens, as well as a once-monthly HIV prevention pill. Because no single medicine works for every person, we are committed to expanding choices that may help address the diverse needs and preferences of people living with HIV or those who could benefit from PrEP."

At HIV Glasgow, Merck will present Phase 3 subgroup analyses of once-daily IDVYNSO, including Week 48 resistance and weight analyses from Trial 53 comparing IDVYNSO to bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) in adults with HIV-1 who had not previously received antiretroviral treatment, as well as Week 96 patient-reported outcomes for IDVYNSO in adults with virologically suppressed HIV-1. Separately, the U.S. Food and Drug Administration (FDA) has accepted two supplemental New Drug Applications for IDVYNSO (doravirine and islatravir): one based on the Phase 3 Trial 053 in adults who had not previously received antiretroviral treatment and one based on the Phase 3 Trials 051 and 052 to include 96-week data in virologically suppressed adults. The FDA has set a Prescription Drug User Fee Act (PDUFA) or target action date of April 22, 2027, for both applications.

IDVYNSO (doravirine/islatravir) is a two-drug single-tablet regimen of 100 mg doravirine and 0.25 mg islatravir and is approved in the United States for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of virologic treatment failure and no known substitutions associated with resistance to doravirine.

The investigational once-weekly oral regimen of islatravir and lenacapavir pairs Merck's islatravir, a potent 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. Data to be presented at HIV Glasgow from the Phase 3 ISLEND-1 and ISLEND-2 trials will include Week 48 safety and efficacy subgroup analyses across diverse demographic populations. ISLEND-2 data will also include Week 48 patient-reported outcomes and a qualitative substudy of participant and provider experiences with once-weekly dosing. These data further characterize **Phase 3 safety and efficacy findings** first presented at AIDS 2026, providing additional insight across patient subgroups, treatment experiences, and preferences with once-weekly oral therapy.

Key presentations at HIV Glasgow 2026 by program:

Doravirine/islatravir (once-daily oral treatment)

- DOR/ISL analyses: Week 48 resistance and weight analyses in adults with HIV-1 who had not previously received antiretroviral treatment and Week 96 patient-reported outcomes assessing treatment satisfaction in adults living with virologically suppressed HIV-1 (Abstract #P060, Abstract #P401, Abstract #P063).

Islatravir/lenacapavir (investigational once-weekly oral treatment)

- ISLEND-1 (Phase 3): Week 48 subgroup analyses evaluating a switch to once-weekly ISL/LEN compared to continuing a daily regimen of BIC/FTC/TAF in adults living with virologically suppressed HIV-1 (Abstract #P050).

- ISLEND-2 (Phase 3): Week 48 subgroup analyses evaluating a switch to once-weekly ISL/LEN compared to continuing daily standard-of-care treatment in adults living with virologically suppressed HIV-1, accompanied by Week 48 patient-reported outcomes and a qualitative substudy detailing participant and provider experiences (Abstract #P049, Abstract #P057, Abstract #P056).

Islatravir + ulonivirine (investigational once-weekly oral treatment)

- Week 24 data from the Phase 2b MK-8591B-060 (**NCT06891066**) study that informed an updated population pharmacokinetic model of ulonivirine. The model characterizes exposure and activity over time to support dosing recommendations for the investigational once-weekly combination of ulonivirine 200 mg and islatravir 2 mg in adults living with virologically suppressed HIV-1 (Abstract #P038).
- Phase 1 clinical pharmacology data on the absorption, metabolism, and excretion profile of investigational ulonivirine (Abstract #P265).

Alimatravir (AMI [MK-8527]; investigational once-monthly oral PrEP)

- AMI is being evaluated as a potential once-monthly oral prevention option for HIV-1 in two ongoing Phase 3 trials. Adult enrollment in both trials is now complete. Participant demographics will be presented from the adult cohorts of EXPrESSIVE-10 and EXPrESSIVE-11 (Abstract #P017, Abstract #P015).

Merck symposia during HIV Glasgow 2026

- Policy symposium:Reimagining HIV elimination: Policy solutions for the next decade
  Date and time: Monday, Nov. 9, 18:15–19:30 GMT/UTC+0, Scottish Event Campus (Clyde Auditorium)
- Medical symposium:Considerations for individualizing HIV care: Cardiometabolic health, unmet needs and the older adult
  Date and time: Tuesday, Nov. 10, 12:45–13:45 GMT/UTC+0, Scottish Event Campus (Clyde Auditorium)

  Both events will be open to registered attendees, in person and virtually.

Details on abstracts listed above and select additional abstracts:

Abstract Title and Presenting Author	
HIV Treatment	
Resistance analysis at Week 48 of daily doravirine/islatravir (100 mg/0.25 mg) versus bictegravir/emtricitabine/tenofovir alafenamide in a blinded Phase 3 study in adults initiating treatment for HIV-1. T. Diamond.	Abstract #P060 Poster Presentation
Evaluation of weight in previously untreated adults living with HIV-1 initiated on doravirine/islatravir (100 mg/0.25 mg) vs bictegravir/emtricitabine/tenofovir alafenamide: Week 48 results from a randomised, double-blind Phase 3 study. J. Rockstroh.	Abstract #P401 Poster Presentation

Patient-reported outcomes with doravirine/islatravir (100/0.25 mg) once daily versus bictegravir/emtricitabine/tenofovir alafenamide in virologically suppressed adults living with HIV-1: Phase 3 results through Week 96. G. Sinclair.	Abstract #P063 Poster Presentation
Once-weekly ulonivirine provides a week of forgiveness after a missed dose. M. Pham.	Abstract #P038 Poster Presentation
Phase 1 study to investigate the absorption, metabolism, and excretion of ulonivirine, a non-nucleoside reverse transcriptase inhibitor, in adults without HIV. G. Gillespie.	Abstract #P265 Poster Presentation
Once-weekly oral islatravir/lenacapavir (ISL/LEN) versus daily bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) in virologically suppressed adults with HIV-1: Week 48 subgroup analyses of the Phase 3 ISLEND-1 trial. J. Rockstroh.*	Abstract #P050 Poster Presentation
Efficacy and safety of once-weekly oral islatravir/lenacapavir (ISL/LEN) versus daily standard of care (SOC) across demographic and clinical subgroups through Week 48 in the Phase 3 ISLEND-2 trial. M. Parczewski.*	Abstract #P049 Poster Presentation
Quality of life and treatment preference with weekly ISL/LEN versus standard of care: Week 48 patient-reported outcome analysis of the Phase 3 ISLEND-2 Study. M. Ramgopal.*	Abstract #P057 Poster Presentation
Understanding treatment experiences with weekly oral islatravir/lenacapavir in the Phase 3 ISLEND-2 study: Participant and provider interviews. C. Orkin.*	Abstract #P056 Poster Presentation
HIV Prevention	
EXPrESSIVE-10: A Phase 3 study evaluating MK-8527 oral once monthly for HIV pre-exposure prophylaxis in cisgender women who are at greater likelihood of HIV exposure. R. Heffron.	Abstract #P017 Poster Presentation
EXPrESSIVE-11: A Phase 3 study evaluating MK-8527 oral once monthly for HIV pre-exposure prophylaxis in cisgender men who have sex with men, transgender women, transgender men, and gender nonbinary individuals who are at greater likelihood of HIV exposure. R. Landovitz; presenting author: R. Plank.	Abstract #P015 Poster Presentation
Phase 1 study to evaluate the effect of a single supratherapeutic dose of MK-8527 on QTc interval prolongation in healthy adults. R. Carstens.	Abstract #P268 Poster Presentation

*In collaboration with Gilead.

About Merck's HIV research

Islatravir (MK-8591) is Merck's potent 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). It is being studied in multiple ongoing early and late-stage clinical trials of two-drug regimens in combination with other antiretrovirals for potential treatments for HIV-1. Islatravir is approved in combination with doravirine as IDVYNSO® (doravirine/islatravir) in the United States and Japan as a once-daily, single-tablet regimen for adults with virologically suppressed HIV-1. It continues to be evaluated in Phase 3 trials in combination with Merck's doravirine as a once-daily regimen for adults who had not previously received antiretroviral treatment; in combination with Gilead's lenacapavir as a novel once-weekly oral treatment for HIV-1 in virologically suppressed adults (ISLEND-1 [**NCT06630286**] and ISLEND-2 [**NCT06630299**]); and in combination with Merck's investigational NNRTI ulonivirine (MK-8507) in Phase 2b development (MK-8591B-060 [**NCT06891066**] and MK-8591B-062 [**NCT07266831**]) as a once-weekly oral regimen.

Alimatravir (MK-8527), an investigational once-monthly oral PrEP, is being evaluated in two Phase 3 clinical trials. With financial support from the Gates Foundation, the Phase 3 EXPrESSIVE-10 trial (MK-8527-010, **NCT07071623**) is evaluating the safety and efficacy of alimatravir in adolescent girls and young women in Kenya, South Africa and Uganda. EXPrESSIVE-11 (MK-8527-011, **NCT07044297**) is evaluating the safety and efficacy of alimatravir among people with greater likelihood of HIV-1 exposure in 16 countries. Adult enrollment in both trials is now complete.

For an overview of Merck's HIV treatment and prevention clinical development program, please click **here**.

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 potentially transformative innovations, collaborations with others in the global HIV community, and access initiatives to help end the HIV epidemic.

Selected Safety Information for IDVYNSO®

Contraindications

IDVYNSO is contraindicated when co-administered with:

- drugs that are strong cytochrome P450 (CYP)3A enzyme inducers as significant decreases in doravirine plasma concentrations may occur, which may decrease the effectiveness of IDVYNSO .
- lamivudine (3TC) or emtricitabine (FTC) as significant decreases in islatravir-triphosphate (ISL-TP) concentrations may occur, which may decrease the effectiveness of IDVYNSO. (See Drug Interactions)

Warnings and Precautions

Severe skin reactions, including Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN), have been reported during postmarketing experience with doravirine-containing regimens. In addition, Drug Rash with Eosinophilia and Systemic Symptoms (DRESS syndrome) was reported with IDVYNSO in a clinical trial. Discontinue IDVYNSO, and other medications associated with these reactions, immediately if a painful rash with mucosal involvement, a progressive severe rash, or a rash with constitutional symptoms, eosinophilia, lymphadenopathy, or other organ involvement develops. Close clinical monitoring and appropriate therapy should be initiated.

The concomitant use of IDVYNSO and certain other drugs may result in known or potentially significant drug interactions, some of which may lead to loss of therapeutic effect of IDVYNSO and possible development of resistance or possible clinically significant adverse reactions from greater exposures of a component of IDVYNSO.

Consider the potential for drug interactions prior to and during IDVYNSO therapy, review concomitant medications during IDVYNSO therapy, and monitor for adverse reactions. (See Drug Interactions)

Adverse Reactions

The most common adverse reactions (incidence ≥2%, all grades in any treatment group) reported in virologically suppressed participants in the IDVYNSO treatment groups in Trials 051 and 052, respectively, were: diarrhea (3% and 1%), dizziness (2% and 1%), fatigue (2% and 1%), abdominal distension (2% and 1%), headache (2% and 1%) and weight increased (2% and <1%).

A single case of severe immune thrombocytopenia (platelet count nadir of 2 x109/L) characterized by abrupt onset of subcutaneous hematoma, petechiae, and hematuria was reported in a participant 32 days after initiating IDVYNSO. The case resolved with discontinuation of IDVYNSO, in conjunction with treatments including corticosteroids and intravenous immunoglobulin (IVIG). Among all participants in Trials 052 and 051, there were no patterns of platelet decreases over time with IDVYNSO and no differences between treatment arms in mean change from baseline in platelet count.

Drug Interactions

IDVYNSO is a complete regimen; co-administration with other antiretroviral medications for treatment of HIV-1 infection is not recommended.

Co-administration of IDVYNSO with a CYP3A inducer decreases doravirine plasma concentrations, which may reduce the efficacy of IDVYNSO. If IDVYNSO is co-administered with rifabutin, one tablet of doravirine should be taken approximately 12 hours after the dose of IDVYNSO. Co-administration of IDVYNSO with other moderate CYP3A inducers is not recommended.

Co-administration of IDVYNSO and drugs that are inhibitors of CYP3A may result in increased plasma concentrations of doravirine.

Co-administration of IDVYNSO is not recommended with deoxycytidine kinase (dCK) substrates (e.g., nucleoside antimetabolites) as they may reduce the exposure of islatravir-triphosphate or with adenosine deaminase (ADA) inhibitors (e.g., pentostatin) as they may increase the exposure of islatravir. (See Contraindications)

Use in Specific Populations

There are insufficient human data on the use of IDVYNSO during pregnancy to inform a drug-associated risk of birth defects and miscarriage. Healthcare providers are encouraged to call the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263 to report pregnancy outcomes in individuals exposed to IDVYNSO.

It is unknown whether IDVYNSO or any of its components are present in human milk, affects human milk production, or has effects on the breastfed infant. Inform patients that the potential risks of breastfeeding include: (1) HIV-1 transmission (in infants without HIV-1), (2) developing viral resistance (in infants with HIV-1), and (3) serious adverse reactions in a breastfed infant similar to those seen in adults.

Clinical trials in virologically suppressed participants who received IDVYNSO included 81 (11%) participants aged 65

years and older, including 10 (1%) aged 75 years and older. Overall differences in response have not been identified between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

No dosage adjustment of IDVYNSO is required in patients with eGFR ≥30 mL/min/1.73 m2. IDVYNSO is not recommended in patients with eGFR <30 mL/min/1.73 m2 and has not been studied in participants undergoing dialysis.

No dosage adjustment of IDVYNSO is recommended in patients with mild or moderate hepatic impairment (Child-Pugh Class A or B). IDVYNSO has not been studied in patients with severe hepatic impairment (Child-Pugh Class C) and therefore is not recommended in these patients.

IDVYNSO does not have activity against hepatitis B virus (HBV). Patients with HBV coinfection who switch to IDVYNSO from an antiretroviral regimen with activity against HBV, and patients on IDVYNSO who are newly diagnosed with HBV coinfection, should be closely monitored and specific anti-HBV therapy should be considered, as clinically appropriate.

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**.

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**).

Please see Prescribing Information for IDVYNSO® (doravirine and islatravir) at **https://www.merck.com/product/usa/pi_circulars/i/idvynso/idvynso_pi.pdf** and Patient Information for IDVYNSO at **https://www.merck.com/product/usa/pi_circulars/i/idvynso/idvynso_ppi.pdf**.

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