NEWS RELEASE

Merck to Present New Data on Daily, Weekly, and Monthly Options Across its HIV Treatment and Prevention Pipeline at AIDS 2026

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Late-breaker presentations will highlight investigational, once-weekly oral combinations of islatravir with lenacapavir (Phase 3 ISL/LEN) and with ulonivirine (Phase 2b ISL+ULO) in adults with virologically-suppressed HIV-1

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that new data from its research pipeline for HIV treatment and prevention will be presented at the 26th International AIDS Conference (AIDS 2026), taking place July 26-31, 2026, in Rio de Janeiro, Brazil.

“Building on the momentum of the recent FDA approval of IDVYNSO, AIDS 2026 is an exciting moment to showcase the next chapter of Merck’s HIV pipeline – particularly our focus on the potential of once-weekly oral treatments in combination with islatravir,” said Dr. Eliav Barr, senior vice president, head of global clinical development and chief medical officer, Merck Research Laboratories. “The breadth of new data spanning our daily, weekly and monthly investigational regimens developed for HIV treatment and prevention demonstrates how Merck’s research is continuing to evolve with the needs of the HIV community.”

Oral late-breaker presentations at AIDS 2026 by program:

Islatravir/Lenacapavir

- Primary results of Week 48 efficacy and safety data from the pivotal, Phase 3 ISLEND-1 trial evaluating switch

to investigational once-weekly oral islatravir and lenacapavir (ISL/LEN) compared to continuing daily regimen of bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) in adults with virologically-suppressed HIV-1 (Abstract #OAB1406LB).

- Primary results of Week 48 efficacy and safety data from pivotal Phase 3 ISLEND-2 trial evaluating switch to investigational once-weekly oral islatravir and lenacapavir (ISL/LEN) compared to continuing daily standard of care in adults with virologically-suppressed HIV-1 (Abstract #OAX1106LB).

Islatravir + Ulonivirine

- Primary results of Week 24 efficacy and safety data from the Phase 2b MK-8591B-060 trial evaluating switch to investigational once-weekly oral islatravir and ulonivirine (ISL + ULO) compared to continuing daily BIC/FTC/TAF in adults with virologically-suppressed HIV-1 (Abstract #OAB1405LB).

Doravirine/Islatravir

- Switching to doravirine/islatravir (100/0.25 mg) once-daily maintained viral suppression at Week 96 in the presence of baseline NNRTI resistance-associated mutations and/or M184I/V in proviral DNA (Abstract #OAB0105LB).

Merck symposia during AIDS 2026

Merck will host a policy symposium entitled “Access where it counts: Expanding PrEP beyond clinics” on Wednesday, July 29, from 18:00 – 19:30 (BRT/UTC-3).

Merck will also host a medical symposium entitled “Evolving standards in HIV care: Resistance, cardiometabolic health, and care for older adults” on Wednesday, July 29, from 12:00 – 13:00 (BRT/UTC-3).

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

Merck Investor Event

Merck will hold a virtual HIV Investor Event on Monday, August 3, 2026, at 8:00 a.m. ET, during which senior management will provide an update on the company’s HIV program and strategy. Investors, analysts, members of the media, and the general public are invited to listen to a webcast of the presentation via this **weblink**. All participants may join the call by dialing (888) 790-1829 (U.S. and Canada Toll-Free) or (210) 839-8800 and using the access code 6773537.

Details on abstracts listed above and select additional abstracts:

Abstract Title and Presenting Author	Date
HIV Treatment	
Once-weekly oral islatravir/lenacapavir (ISL/LEN) versus daily bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in virologically-suppressed adults with HIV-1: Week 48 results of the ISLEND-1 phase 3 trial. J. Rockstroh.*	Abstract #OAB1406LB Oral Presentation ARTistic Strategies 2: The Long Game Wednesday, July 29, 2026 15:00-16:00 PM BRT
Once-weekly oral islatravir/lenacapavir (ISL/LEN) versus daily standard-of-care therapy in virologically-suppressed adults with HIV-1: week 48 results of the ISLEND-2 phase 3 trial. A. Colson.*	Abstract #OAX1106LB Oral Presentation AIDS 2026: Co-Chair's Choice Wednesday, July 29, 2026 10:30-11:30 AM BRT
Randomized, active-controlled, phase 2b study evaluating efficacy and safety of switch to islatravir (ISL) 2 mg with ulonivirine (ULO) 200 mg once-weekly in virologically suppressed adults living with HIV-1. A. Luetkemeyer.	Abstract #OAB1405LB Oral Presentation ARTistic Strategies 2: The Long Game Wednesday, July 29, 2026 15:00-16:00 PM BRT
Switching to doravirine/islatravir (100/0.25mg) once-daily maintained viral suppression at week 96 in the presence of baseline NNRTI resistance-associated mutations and/or M184I/V in proviral DNA. T. Diamond.	Abstract #OAB0105LB Oral Presentation ARTistic Strategies 1: From Testing to Treatment Tuesday, July 28, 2026 10:30-11:30 AM BRT
Simplification to single-tablet doravirine/islatravir from complex antiretroviral regimens: subgroup analysis from a randomized, open-label, phase 3 clinical study. M. Fox.	Abstract #LB23 Poster exhibition Tuesday, July 28, 2026 Wednesday, July 29, 2026 Thursday, July 30, 2026 12:00-1:00 PM BRT
Efficacy and safety by subgroup of doravirine/islatravir (100 mg/0.25 mg) once daily as initial HIV-1 therapy: week 48 results from a randomized, active-controlled Phase 3 study. B. Crabtree-Ramírez.	Abstract #WEPEB089 Poster exhibition Wednesday, July 29, 2026 12:00-1:00 PM BRT
Open-label Phase 1 study to evaluate relative bioavailability and food effect on the pharmacokinetics of the fixed-dose combination of doravirine/islatravir (100 mg/0.25 mg) in adults without HIV. S. Stanley.	Abstract #EP054 E-poster Monday, July 27, 2026 14:00 PM BRT
Comorbidity and comedication burden in people living with HIV stratified by age and sex. S. Fleming.	Abstract #TUPEB079 Poster exhibition Tuesday, July 28, 2026 12:00-1:00 PM BRT
Opti-DOR: 48-week data on DOR/3TC/TDF as an alternative first-line antiretroviral therapy (ART) regimen to integrase inhibitors for people with HIV and BMI>25 kg/m2 in a randomized Phase 3b non-inferiority study. J. Woods.**	Abstract #OAB3406LB Oral Presentation Metabolic complications: The eye of the storm Friday, July 31, 2026 10:30-11:30 AM BRT
HIV Prevention	
MK-8527 de novo resistance selection in HIV-1 subtypes A, B, and C and prevalence of M184I/V mutations in persons diagnosed with HIV without a known history of HIV treatment. T. Diamond.	Abstract #LB27 Poster exhibition Tuesday, July 28, 2026 Wednesday, July 29, 2026 Thursday, July 30, 2026 12:00-13:00 PM BRT
Open-label Phase 1 study to characterize the effects of a strong CYP3A4 inducer on the pharmacokinetics of MK-8527, a nucleoside reverse transcriptase translocation inhibitor, in adults without HIV. R. Carstens.	Abstract #TUPEB125 Poster exhibition Tuesday, July 28, 2026 12:00-1:00 PM BRT
Open-label Phase 1 study of the effects of emtricitabine and tenofovir disoproxil fumarate on the pharmacokinetics of MK-8527, a nucleoside reverse transcriptase translocation inhibitor, in adults without HIV. R. Carstens.	Abstract #WEPEC183 Poster exhibition Wednesday, July 29, 2026 12:00-1:00 PM BRT
Features of HIV-1 acquisition in adults receiving pre-exposure prophylaxis as part of the IMPOWER-22 and IMPOWER-24 open-label phase. R. Landovitz.	Abstract #WEPEC175 Poster exhibition Wednesday, July 29, 2026 12:00-1:00 PM BRT
PrEP modality preferences by psychosocial phenotypes of gay, bisexual, and other men who have sex with men using latent class analysis. R. Gravett.	Abstract #TUPEC172 Poster exhibition Tuesday, July 28, 2026 12:00-1:00 PM BRT

*In collaboration with Gilead
**Merck-supported, investigator-initiated study

About islatravir (MK-8591) and Merck's HIV research

Islatravir (MK-8591) is Merck's potent, next-generation nucleoside analog reverse transcriptase inhibitor 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 under evaluation in multiple ongoing early and late-stage clinical trials in combination with other antiretrovirals for potential treatments for HIV-1.

Islatravir is available in combination with Merck's s non-nucleoside reverse transcriptase inhibitor (NNRTI), doravirine, in the United States and Japan as IDVYNSO™, a new, once-daily, single-tablet regimen 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.

Islatravir continues to be 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; in combination with Gilead's lenacapavir in Phase 3 development as a novel once-weekly oral treatment for HIV-1 (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 an once-weekly oral treatment.

MK-8527 (alimatravir) is the company's investigational, novel, once-monthly oral candidate for pre-exposure prophylaxis (PrEP) for HIV-1. In collaboration with the Gates Foundation, the Phase 3 EXPrESSIVE-10 trial (MK-8527-010, **NCT07071623**) is evaluating the safety and efficacy of MK-8527 as PrEP to reduce the risk of sexually acquired HIV-1 infection among women and adolescent girls in sub-Saharan Africa. The Phase 3 EXPrESSIVE-11 trial (MK-8527-011, **NCT07044297**) is evaluating the safety and efficacy of MK-8527 as PrEP to reduce the risk of sexually acquired HIV-1 infection among people likely to be exposed to HIV-1 in 16 countries. Both trials are now enrolling.

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 transformational 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 and 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 from 2 clinical trials, respectively, were: diarrhea (3% and 1%), dizziness (2% and 1%), fatigue (2% and 1%), abdominal distension (2% and 1%), headache (2% and 1%) and increased weight (2% and <1%).

A single case of severe immune thrombocytopenia (platelet count nadir of 2 $x10^9$/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 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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