NEWS RELEASE

Merck Announces New Agreement with ADAP Crisis Task Force to Improve Access and Care for People Living with HIV

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Agreement will help state ADAP programs provide access to IDVYNSO™ (doravirine/islatravir) for eligible individuals

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced an agreement with the ADAP Crisis Task Force (ACTF) to help state AIDS Drug Assistance Programs (ADAPs) provide access to the company's new once-daily HIV treatment, IDVYNSO™ (doravirine/islatravir). In 2024, state ADAPs supported more than 250,000 people with HIV in the United States.

IDVYNSO was approved by the U.S. Food and Drug Administration (FDA) in April 2026 as a new, two-drug single-tablet regimen of 100 mg doravirine and 0.25 mg islatravir, 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.

"ADAP programs play a critical role in supporting access to treatment for people living with HIV who are uninsured or underserved," said Tim Horn, Director, Medication Access, National Alliance of State and Territorial AIDS Directors (NASTAD). "We appreciate Merck's continued engagement and its willingness to work collaboratively to help address the critical access challenges facing state ADAP programs."

"Merck is pleased to have reached this agreement with the ADAP Crisis Task Force to expand access to IDVYNSO for

eligible people with HIV," said Conrod Kelly, U.S. HIV business unit head, Merck. "This agreement reflects our long-standing commitment to working with the ACTF, state ADAPs and the HIV community to strengthen access and help address persistent gaps in care."

For individuals with questions about coverage and affordability, the Merck Access Program may be able to provide information about insurance benefits, estimated out-of-pocket costs and co-pay assistance options for eligible patients.

The Merck Access Program for IDVYNSO

Merck offers support to individuals who are prescribed IDVYNSO, including information about patient insurance coverage and out-of-pocket costs, co-pay assistance for eligible, commercially insured individuals, and how individuals may access IDVYNSO through The Merck Access Program. For additional information, healthcare providers and individuals can call 1-877-709-4455 or visit **https://www.merckaccessprogram-idvynso.com/**.

About IDVYNSO

IDVYNSO is a fixed-dose combination of two medicines, doravirine and islatravir. Doravirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI) that inhibits HIV-1 replication by non-competitive inhibition of HIV-1 reverse transcriptase. Islatravir is a potent, next-generation nucleoside analog reverse transcriptase inhibitor (NRTI) 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).

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.

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 Islatravir (MK-8591) and Merck's HIV Research

Islatravir (MK-8591) is Merck's potent, next-generation nucleoside analog reverse transcriptase inhibitor (NRTI) 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 approved in combination with Merck's NNRTI, doravirine, in the United States and Japan as IDVYNSO™, a 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 is also under evaluation in multiple ongoing early and late-stage clinical trials in combination with other antiretrovirals for potential once-weekly treatments for HIV-1, in Merck's proprietary two-drug regimens.

Islatravir in combination with Gilead's lenacapavir is in Phase 3 development as a novel oral once-weekly treatment for HIV-1 [ISLEND-1 (**NCT06630286**) and ISLEND-2 (**NCT06630299**)], and islatravir in combination with Merck's investigational non-nucleoside reverse transcriptase inhibitor (NNRTI) ulonivirine (MK-8507) is in Phase 2b development (MK-8591B-060, **NCT06891066** and MK-8591B-062, **NCT07266831**) as an oral once-weekly treatment.

MK-8527 is Merck'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**) trial 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**) in 16 countries 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. Both trials are now enrolling.

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

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. 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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