News Release

FDA Approves Merck's Once-Daily IDVYNSO™ (doravirine/islatravir)

IDVYNSO is approved for adults with virologically suppressed HIV-1 with no history of virologic treatment failure and no known substitutions associated with resistance to doravirine

IDVYNSO is the first and only non-INSTI, tenofovir-free, once-daily, complete two-drug regimen to demonstrate non-inferior efficacy in a head-to-head Phase 3 trial versus three-drug regimen BIKTARVY®[i] (BIC/FTC/TAF)

RAHWAY, N.J., April 21, 2026 – Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that the U.S. Food and Drug Administration (FDA) approved IDVYNSO™, 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. IDVYNSO is contraindicated when co-administered with drugs that are strong cytochrome P450 (CYP)3A enzyme inducers and lamivudine (3TC) or emtricitabine (FTC). Co-administration with these drugs may decrease the effectiveness of IDVYNSO. *See additional selected safety information on the following pages*. IDVYNSO (pronounced ihd-VIHN-soh) will be available in pharmacies after May 11.

"Advances in HIV treatment mean more people living with HIV are living longer — a remarkable achievement," said Carl Baloney, Jr., president and chief executive officer of AIDS United. "People aging with HIV face additional health challenges, including managing multiple chronic conditions and medications at the same time. It is essential that management of HIV considers these factors in addition to virologic suppression when choosing an HIV treatment regimen."

"IDVYNSO combines islatravir, a next-generation NRTI with multiple mechanisms of action, including translocation inhibition, with doravirine, an NNRTI with an established efficacy and safety profile. As the only two-drug, non-INSTI, tenofovir-free regimen, IDVYNSO expands therapeutic diversity beyond the currently available oral treatment options," said Dr. Eliav Barr, senior vice president and chief medical officer, Merck Research Laboratories. "As the health needs of adults living with HIV change over time, IDVYNSO gives clinicians a new choice for HIV treatment. This approval marks an important new chapter in Merck's long-standing commitment to research and discovery for people living with HIV."

IDVYNSO is a complete regimen; co-administration with other antiretroviral medications for treatment of HIV-1 infection is not recommended. Severe skin reactions, including Stevens-Johnson syndrome/toxic epidermal necrolysis, have been reported with doravirine-containing

regimens. Drug Rash with Eosinophilia and Systemic Symptoms was reported with IDVYNSO. 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. *See additional selected safety information on the following pages.*

"IDVYNSO is the first non-INSTI, tenofovir-free, two-drug regimen to demonstrate non-inferior efficacy to standard oral antiretroviral regimens, including BIKTARVY. This makes IDVYNSO a potential alternative for people with virologically suppressed HIV who may need to switch their treatment," said Dr. Amy Colson, director of research at Community Resource Initiative, Boston, Massachusetts.

Phase 3 studies supporting approval of IDVYNSO

The efficacy and safety of IDVYNSO is supported by Week 48 data from two randomized, active-controlled, non-inferiority trials [Trial 052 (NCT05630755) and Trial 051 (NCT05631093)] in virologically-suppressed (HIV-1 RNA less than 50 copies per mL) adults living with HIV. Participants must have been stably suppressed on their baseline regimen for at least 3 months prior to trial entry and had no history of treatment failure. Across the two trials, a total of 708 participants received once-daily IDVYNSO; of these, 81 (11%) participants were aged 65 years and older, including 10 (1%) aged 75 years and older.

In the double-blind Trial 052, participants were switched from BIKTARVY [bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF)] to IDVYNSO. A total of 513 participants were randomized (2:1) and were switched to once-daily IDVYNSO (n=342) or remained on BIC/FTC/TAF (n=171). At baseline, participants had a mean age of 48 years (range: 19 to 77), 21% of participants were female, 61% were White, 31% were Black/African American, and 6% were Asian. A total of 23% identified as Hispanic/Latino.

In the open-label Trial 051, participants were switched from an oral ART (antiretroviral therapy) regimen to IDVYNSO. A total of 551 participants were randomized (2:1) and were switched to once-daily IDVYNSO (n=366) or remained on their baseline ART (bART) (n=185). Randomization was stratified by bART. At baseline, participants had a mean age of 50 years (range: 18 to 83), 40% of participants were female, 39% were White, 45% were Black/African American, and 5% were Asian. A total of 15% identified as Hispanic/Latino. At enrollment, 64% of the participants were receiving integrase strand transfer inhibitor (INSTI)-based regimens, 5% protease inhibitor (PI)-based regimens (including combinations with INSTI), and 30% were receiving other regimens.

Efficacy profile of IDVYNSO

IDVYNSO was non-inferior to BIC/FTC/TAF (in Trial 052) and bART (in Trial 051) as assessed by the proportion of participants with HIV-1 RNA ≥50 copies/mL at Week 48.

- In the double-blind Trial 052, results for the primary endpoint (HIV-1 RNA ≥50 copies/mL) showed that 1% of participants who were switched to IDVYNSO (n=342) had a viral load of ≥50 copies/mL at Week 48, compared to 1% who continued on

BIC/FTC/TAF (n=171; treatment difference 0.9%, 95% CI, -1.9%, 2.9%). At Week 48, results from the secondary endpoint showed that 92% of participants who switched to IDVYNSO maintained viral suppression (HIV-1 RNA <50 copies/mL) compared to 94% of participants who continued receiving BIC/FTC/TAF.

- In the open-label Trial 051, results for the primary endpoint (HIV-1 RNA ≥50 copies/mL) showed that 1% of participants who were switched to IDVYNSO (n=366) had a viral load of ≥50 copies/mL at Week 48, compared to 5% who continued on bART (n=185; treatment difference -3.6%, 95% CI, -7.8%, -0.8%). At Week 48, results from the secondary endpoint showed that 96% of participants who switched to IDVYNSO maintained viral suppression (HIV-1 RNA <50 copies/mL) compared to 92% of participants who continued on bART.

In both trials, treatment outcomes between treatment groups were similar across subgroups by age, sex and race, and in Trial 051, also by bART regimens. In participants aged 65 years and older who received IDVYNSO in both trials, no overall differences in safety or effectiveness were observed between these participants and younger participants, but greater sensitivity of some older individuals cannot be ruled out.

Safety and tolerability profile of IDVYNSO

The safety profile of IDVYNSO was generally comparable to BIC/FTC/TAF in Trial 052 and to oral bART regimens in Trial 051. In Trial 052, by Week 48, 3% in the IDVYNSO group and 2% in the BIC/FTC/TAF group had adverse events leading to discontinuation of study medication. In Trial 051, by Week 48, 0.5% in the IDVYNSO group and 2% in the bART group had adverse events leading to discontinuation of study medication.

The most common adverse reactions (all grades) reported in greater than or equal to 2% of participants in any treatment group in Trials 052 and 051 through Week 48 were as follows:

- In Trial 052 (IDVYNSO vs BIC/FTC/TAF, respectively): diarrhea (1% vs 1%), dizziness (1% vs 0%), fatigue (1% vs 1%), abdominal distention (1% vs 0%), headache (1% vs 0%), weight increase (less than 1% vs 0%).
- In Trial 051 (IDVYNSO vs bART, respectively): diarrhea (3% vs 0%), dizziness (2% vs 1%), fatigue (2% vs 1%), abdominal distention (2% vs 0%), headache (2% vs 1%), weight increase (2% vs 0%).

Trial participants taking IDVYNSO had minimal change in weight from baseline. The mean change in weight from baseline at Week 48 was -0.03 kg in the IDVYNSO group vs. 0.28 kg in the BIC/FTC/TAF group in Trial 052 and 0.94 kg in the IDVYNSO group vs. -0.15 kg in the bART group in Trial 051. Four of the six participants with adverse reactions of weight increased switched from a bART regimen containing efavirenz and/or tenofovir disoproxil fumarate in Trial 051.

The Merck Access Program for IDVYNSO

Merck offers support to individuals who are prescribed IDVYNSO, including information about individual 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 merckaccessprogram-IDVYNSO.com.

About IDVYNSO

IDVYNSO is a fixed-dose combination of two medicines, doravirine with 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 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

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.

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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[i] IDVYNSO™ is a trademark of Merck & Co., Inc. BIKTARVY® is a registered trademark of Gilead Sciences Ireland UC.