NEWS RELEASE

Merck to Present New Data from Various HIV Research and Development Programs at CROI 2021

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KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced today upcoming presentations from its HIV clinical development programs that will be featured during the **2021 Conference on Retroviruses and Opportunistic Infections** (CROI 2021), taking place virtually from March 6 – 10, 2021. Presentations will include new data for islatravir, the company's investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI), which is being developed for HIV treatment and prevention. Merck will share late-breaking Phase 1 study results evaluating a new prototype subdermal drug-eluting implant for extended administration of islatravir for pre-exposure prophylaxis (PrEP). This data will also be featured in the CROI virtual press conference. Throughout the conference, Merck will also share pharmacokinetic (PK) threshold and dose selection data for once-monthly oral islatravir for PrEP and model-informed dose selection data for the Phase 2b study of islatravir administered with MK-8507, the company's investigational non-nucleoside reverse transcriptase inhibitor (NNRTI), for oral once-weekly treatment of HIV-1 infection in adults. There will also be updates from the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network evaluating DELSTRIGO™ (doravirine 100 mg/lamivudine 300 mg/tenofovir disoproxil fumarate 300 mg) in HIV-infected adolescents ages 12 to 18 years and weighing at least 45 kg.

"We recognize that new strategies for HIV treatment and prevention continue to be needed to address this global epidemic. We look forward to sharing updates from our broad HIV program at CROI," said Dr. Joan Butterton, vice president, global clinical development, infectious diseases, Merck Research Laboratories. "Our steadfast commitment to the global HIV community is reflected in our exploration of different modalities and combinations and extended duration alternatives for treatment and/or prevention. Merck has been at the forefront of innovation in HIV for decades, and we are excited to continue contributing to HIV research by exploring the development of

longer-acting treatment and prevention options that may help address the evolving needs of people living with or at risk for HIV."

Select abstracts in the CROI 2021 program include:

- Next-Generation Islatravir Implants Projected to Provide Yearly HIV Prophylaxis. Late Breaking Oral Presentation. R. Matthews et al.
- Islatravir PK Threshold & Dose Selection for Monthly Oral HIV-1 PrEP. Oral Presentation. M. Patel et al.
- Resistance Profile of MK-8507, a Novel NNRTI Suitable for Weekly Oral HIV Treatment. Oral Presentation. T. Diamond et al.
- Model Informed Dose Selection for Islatravir/MK-8507 Oral Once-Weekly Phase 2b Study. Science Spotlight Presentation. B. Kandala et al.
- IMPAACT 2014 24-Week PK and Safety of Doravirine/3TC/TDF in Adolescents with HIV-1. Science Spotlight Presentation. A. Melvin et al.
- Week 96 Analysis of Viral Blips from a Phase 2B Trial of Islatravir and Doravirine. Science Spotlight Presentation. C. Orkin et al.
- Comorbidity Burden in People Living with HIV in the United States. Science Spotlight Presentation. P. Kumar et al.
- Improved Detection of HIV Gag p24 Protein from Patient-Derived Samples. Science Spotlight Presentation. P. Zuck et al.

For more information, including details around the virtual programming, please visit the **CROI 2021 website**.

Indications and Usage for DELSTRIGO

DELSTRIGO is indicated as a complete regimen for the treatment of HIV-1 infection in adult patients with no prior ARV treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable ARV regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of DELSTRIGO.

Selected Safety Information about DELSTRIGO

Warning: Posttreatment Acute Exacerbation of Hepatitis B (HBV)

All patients with HIV-1 should be tested for the presence of HBV before initiating ARV therapy. Severe acute exacerbations of HBV have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued products containing lamivudine or tenofovir disoproxil fumarate (TDF), which are components of

DELSTRIGO. Patients coinfected with HIV-1 and HBV who discontinue DELSTRIGO should be monitored with both clinical and laboratory follow-up for at least several months after stopping DELSTRIGO. If appropriate, initiation of anti-HBV therapy may be warranted.

DELSTRIGO is contraindicated when co-administered with drugs that are strong cytochrome P450 (CYP)3A enzyme inducers (including the anticonvulsants carbamazepine, oxcarbazepine, phenobarbital, and phenytoin; the androgen receptor inhibitor enzalutamide; the antimycobacterials rifampin and rifapentine; the cytotoxic agent mitotane; and the herbal product St. John's wort (Hypericum perforatum)), as significant decreases in doravirine plasma concentrations may occur, which may decrease the effectiveness of DELSTRIGO.

DELSTRIGO is contraindicated in patients with a previous hypersensitivity reaction to lamivudine.

Renal impairment, including cases of acute renal failure and Fanconi syndrome, have been reported with the use of TDF. DELSTRIGO should be avoided with concurrent or recent use of a nephrotoxic agent (eg, high-dose or multiple NSAIDs). Cases of acute renal failure after initiation of high-dose or multiple NSAIDs have been reported in patients with risk factors for renal dysfunction who appeared stable on TDF.

Prior to or when initiating DELSTRIGO, and during treatment, assess serum creatinine, estimated creatinine clearance, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus. Discontinue DELSTRIGO in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome. Discontinue DELSTRIGO if estimated creatinine clearance declines below 50 mL/min.

In clinical trials in HIV-1 infected adults, TDF was associated with slightly greater decreases in bone mineral density (BMD) and increases in biochemical markers of bone metabolism. Serum parathyroid hormone levels and 1,25 Vitamin D levels were also higher. Cases of osteomalacia associated with proximal renal tubulopathy have been reported with the use of TDF.

Immune reconstitution syndrome can occur, including the occurrence of autoimmune disorders with variable time to onset, which may necessitate further evaluation and treatment.

Because DELSTRIGO is a complete regimen, co-administration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.

Consult the full Prescribing Information prior to and during treatment for more information on potential drug-drug interactions.

If co-administered with rifabutin, take one tablet of DELSTRIGO once daily, followed by one tablet of doravirine (PIFELTRO) approximately 12 hours after the dose of DELSTRIGO.

Because DELSTRIGO is a fixed-dose combination tablet and the dosage of lamivudine and TDF cannot be adjusted, DELSTRIGO is not recommended in patients with estimated creatinine clearance less than 50 mL/min.

The most common adverse reactions with DELSTRIGO (incidence ≥5%, all intensities) were dizziness (7%), nausea (5%), and abnormal dreams (5%).

By Week 96 in DRIVE-AHEAD, 3% of adult subjects in the DELSTRIGO group and 7% in the EFV/FTC/TDF group had adverse events leading to discontinuation of study medication.

In DRIVE-AHEAD, mean changes from baseline at Week 48 in LDL-cholesterol (LDL-C) and non-HDL-cholesterol (non-HDL-C) were pre-specified. LDL-C: -2.1 mg/dL in the DELSTRIGO group vs 8.3 mg/dL in the EFV/FTC/TDF group. Non-HDL-C: -4.1 mg/dL in the DELSTRIGO group vs 12.7 mg/dL in the EFV/FTC/TDF group. The clinical benefits of these findings have not been demonstrated.

In DRIVE-AHEAD, neuropsychiatric adverse events were reported in the three pre-specified categories of sleep disorders and disturbances, dizziness, and altered sensorium. Twelve percent of adult subjects in the DELSTRIGO group and 26% in the EFV/FTC/TDF group reported neuropsychiatric adverse events of sleep disorders and disturbances; 9% in the DELSTRIGO group and 37% in the EFV/FTC/TDF group reported dizziness; and 4% in the DELSTRIGO group and 8% in the EFV/FTC/TDF group reported altered sensorium.

The safety of DELSTRIGO in virologically-suppressed adults was based on Week 48 data from subjects in the DRIVE-SHIFT trial. Overall, the safety profile in virologically-suppressed adult subjects was similar to that in subjects with no ARV treatment history.

In DRIVE-SHIFT, mean changes from baseline at Week 48 in LDL-cholesterol (LDL-C) and non-HDL-cholesterol (non-HDL-C) were pre-specified. LDL-C: -16.3 mg/dL in the DELSTRIGO group vs -2.6 mg/dL in the PI + ritonavir group. Non-HDL-C: -24.8 mg/dL DELSTRIGO group vs -2.1 mg/dL in the PI + ritonavir group. The clinical benefits of these findings have not been demonstrated.

There is a pregnancy exposure registry that monitors pregnancy outcomes in individuals exposed to PIFELTRO or DELSTRIGO during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263.

Mothers infected with HIV-1 should be instructed not to breastfeed if they are receiving DELSTRIGO due to the

potential for HIV-1 transmission.

About Islatravir (MK-8591)

Islatravir (formerly MK-8591) is Merck's investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) under evaluation in clinical trials for the treatment of HIV-1 infection in combination with other antiretrovirals, including the ILLUMINATE clinical trials program for once-daily treatment, as well as for pre-exposure prophylaxis (PrEP) of HIV-1 infection as a single agent, across a variety of formulations.

Our Commitment to HIV

For more than 35 years, Merck has been committed to scientific research and discovery in HIV, and we continue to be driven by the conviction that more medical advances are still to come. Our focus is on pursuing research that addresses unmet medical needs and helps people living with HIV and their communities. We remain committed to working hand-in-hand with our partners in the global HIV community to address the complex challenges that hinder continued progress toward ending the epidemic.

Our Commitment to Infectious Diseases

For more than 100 years, Merck has contributed to the discovery and development of novel medicines and vaccines to combat infectious diseases. In addition to a combined portfolio of vaccines and antibacterial, antiviral and antifungal medicines, Merck has multiple programs that span discovery through late-stage development. To learn more about Merck's infectious diseases pipeline, visit **www.merck.com**.

About Merck

For 130 years, Merck, known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. For more information, visit **www.merck.com** and connect with us on **Twitter**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, 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 products that the products 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 the global outbreak of novel coronavirus disease (COVID-19); 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 2020 Annual Report on Form 10-K 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 DELSTRIGO (doravirine/3TC/TDF) at: **https://www.merck.com/product/usa/pi_circulars/d/delstrigo/delstrigo_pi.pdf** and Patient Information for DELSTRIGO (doravirine/3TC/TDF) at: **https://www.merck.com/product/usa/pi_circulars/d/delstrigo/delstrigo_ppi.pdf**

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