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NEWS RELEASE

Merck Presents New Data from Ongoing Phase 2a Clinical Trial Evaluating the Safety, Tolerability and Pharmacokinetics of Investigational, Once-Monthly, Oral Islatravir for HIV-1 Prevention at IAS 2021

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Results from this study support the safety profile of oral islatravir PrEP regimen through 24 weeks versus placebo

KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced results from a Phase 2a clinical trial evaluating the safety, tolerability and pharmacokinetics (PK) of six monthly oral doses, over 24 weeks, of islatravir, the company's investigational nucleoside reverse transcriptase translocation inhibitor, versus placebo for pre-exposure prophylaxis (PrEP) of HIV-1 infection in adults at low-risk of contracting HIV-1. After 24 weeks, once-monthly oral islatravir was generally well tolerated versus placebo. Most adverse events (AEs) were mild and there were no serious drug-related AEs in people who received islatravir. The levels of islatravir in peripheral blood mononuclear cells (PBMCs) also remained above the pre-specified efficacy PK threshold for PrEP at both doses studied (60 mg and 120 mg) eight weeks after the last study dose. These data were shared as a late-breaking oral presentation during the virtual **11th International AIDS Society Conference on HIV Science** (IAS 2021) and are a follow-up to the interim analysis that was **presented** earlier this year at the virtual 2021 HIV Research for Prevention Conference (HIVR4P 2021).

"The 24-week analysis of investigational, once-monthly oral islatravir not only builds upon the PK data we have already seen, but also provides encouraging support for the safety and tolerability profile of this HIV-1 PrEP regimen," said Dr. Joan Butterton, vice president, global clinical development, infectious diseases, Merck Research Laboratories. "As part of our commitment to understanding the potential for our HIV medicines in a broad range of

patients, we focused on the enrollment of diverse patient populations at risk for HIV, including women, who have one of the highest unmet needs in HIV prevention."

Islatravir is currently being evaluated across a variety of dosing regimens, for both the treatment of HIV-1 infection in combination with other antiretroviral agents and for the prevention of HIV-1 infection as a monotherapy. An overview of the islatravir treatment and prevention development program is available **here**, which includes our two Phase 3 IMPOWER trials evaluating islatravir as once-monthly oral PrEP across diverse populations of people who may benefit from additional HIV-1 prevention options.

Phase 2a Oral Study Results for Investigational Islatravir

In the ongoing Phase 2a (NCT04003103) randomized, double-blind, parallel assignment, placebo-controlled, multicenter trial in adults at low-risk for acquiring HIV-1 infection, participants were randomly assigned (2:2:1) to one of three oral once-monthly therapy groups: islatravir 60 mg, islatravir 120 mg or placebo. Participants received once monthly oral doses of islatravir or placebo over a 24-week blinded therapy period, followed by a 12-week blinded follow-up in all groups and a 32-week unblinded follow-up in the islatravir groups to characterize the terminal elimination phase. Outcome measures for safety, tolerability and PK will be analyzed through week 68.

Of the 242 randomized participants at this 24-week analysis, which concludes the dosing portion of the study, 92% (n=222/242) completed dosing and 8% (n=20/242) discontinued the study intervention before week 24. Less than 1% (n=2) of participants discontinued due to an AE. Of the total participants, 67.4% (n=163/242) were female, 52.9% (n=128/242) were white, 41.7% (n=101/242) were Black or African American and 14.9% (n=36/242) were Hispanic or Latino. Unblinded safety data showed that both doses of islatravir were generally well tolerated versus placebo over 24 weeks and most AEs were mild (73.5%). The most common AEs (occurring in $\geq$5% of participants) in the islatravir 60 mg, islatravir 120 mg and placebo groups respectively were headache (10.3% [n=10/97], 9.3% [n=9/97] and 4.2% [n=2/48]), diarrhea (5.2% [n=5/97], 5.2% [n=5/97] and 8.3% [n=4/48]) and nausea (5.2% [n=5/97]), 7.2% [n=7/97] and 4.2% [n=2/48]). There were no serious drug-related AEs in people who received islatravir. The study enrolled a population at low-risk for HIV infection as evidenced by no confirmed HIV infections occurring during the treatment period.

The PK analysis showed that trough concentrations (the lowest level between doses) of islatravir triphosphate in PBMCs following either 60 mg or 120 mg monthly doses continue to remain above the pre-specified PK threshold for HIV-1 prophylaxis of 0.05 pmol/106 PBMCs and were sustained through eight weeks after the last dose of islatravir.

About Islatravir (MK-8591)

Islatravir (MK-8591) is Merck's investigational nucleoside reverse transcriptase translocation inhibitor 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. Islatravir is also being studied for pre-exposure prophylaxis (PrEP) of HIV-1 infection as a single agent across a variety of formulations, including the IMPOWER clinical trials evaluating an oral once-monthly regimen.

Our Commitment to HIV

For more than 35 years, Merck has been committed to scientific research and discovery (R&D) in HIV. Today, we are developing a series of antiviral options designed to help people manage HIV and protect people from HIV, with the goal of reducing the growing burden of infection worldwide. We remain committed to working hand-in-hand with our partners in the global HIV community to address the complex challenges that impede progress toward ending the epidemic.

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**).

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