Merck to Initiate New Phase 3 Clinical Program with Lower Dose of Daily Oral Islatravir in Combination with Doravirine for Treatment of People with HIV-1 Infection

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Phase 2 study evaluating an investigational weekly oral combination treatment regimen of islatravir and Gilead Sciences’ lenacapavir to resume with lower dose of islatravir

Monthly oral islatravir development for pre-exposure prophylaxis (PrEP) to be discontinued; Merck continues to evaluate other long-acting PrEP candidates

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that the company will initiate a new Phase 3 clinical program with once-daily islatravir for the treatment of people with HIV-1 infection. These new Phase 3 studies will evaluate a once-daily oral combination of doravirine 100 mg and a lower dose of islatravir (DOR/ISL). One study will evaluate DOR/ISL in previously untreated adults with HIV-1 infection and two studies will evaluate DOR/ISL as a switch in antiretroviral therapy (ART) in adults with HIV-1 infection who are virologically suppressed. Certain study participants currently enrolled in once-daily treatment studies with DOR 100 mg/ISL 0.75 mg will have the option of transitioning to a new study with the lower islatravir dose. The U.S. Food and Drug Administration (FDA) has reviewed and agreed with this plan. The investigational new drug application (IND) for the once-daily oral DOR/ISL treatment program remains under a partial clinical hold for any studies that would use doses higher than the dose to be studied in the new Phase 3 program. Refer here for more information on the islatravir clinical hold.

The Phase 2 clinical trial (NCT05052996) evaluating an investigational oral once-weekly combination treatment
regimen of islatravir and Gilead’s lenacapavir in adults with HIV-1 infection who are virologically suppressed will resume under an amended protocol with a lower dose of islatravir. The IND under which the islatravir + lenacapavir once-weekly treatment regimen is being investigated remains under a partial clinical hold for any studies that would use weekly oral islatravir doses higher than the doses considered for the revised clinical program. Islatravir and lenacapavir, in combination, are investigational and not approved for use. The safety and efficacy of this combination has not yet been established.

Additionally, after careful evaluation and analysis, Merck will discontinue the development of once-monthly oral islatravir for PrEP. Participants in the ongoing Phase 3 PrEP once-monthly oral studies will continue to be monitored. The company remains committed to developing compounds for long-acting HIV prevention and believes in the potential of the nucleoside reverse transcriptase translocation inhibitor (NRTTI) mechanism. A Phase 1b study in adults with HIV-1 infection assessing MK-8527, a novel NRTTI candidate, will commence shortly (NCT05494736). Merck will continue to engage with key stakeholders as it works to help address the unmet need in HIV prevention.

“We are grateful to the study investigators and the many participants in the trials of islatravir. Following extensive evaluations and consultation with FDA, we are pleased to be able to initiate our new Phase 3 clinical program to evaluate islatravir for the treatment of HIV-1 infection,” said Dr. Eliav Barr, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. “We continue to believe in the potential of the NRTTI mechanism and we are evaluating additional candidates with the goal of helping to address unmet needs in HIV prevention. As part of this, we are pleased to continue our partnership with the Bill & Melinda Gates Foundation as we continue to evaluate potential long-acting PrEP opportunities.”

Merck’s 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

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 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 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 Annual Report on Form 10-K for the year ended December 31, 2021 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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