Merck Opens Enrollment in New Phase 3 Clinical Trials with Investigational Once-Daily Islatravir in Combination with Doravirine for Treatment of HIV-1 Infection

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Islatravir and other HIV data presented at CROI 2023

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that the company has opened enrollment in its new Phase 3 clinical program with investigational once-daily islatravir 0.25 mg in combination with doravirine 100 mg (DOR/ISL) for the treatment of HIV-1 infection.

“Our extensive efficacy and safety analyses from the islatravir clinical program over the past year provided critical information to shape our research going forward,” said Todd Correll, executive director, DOR/ISL product development team lead, Merck Research Laboratories. “We believe islatravir in combination with doravirine has the potential to help make a difference for people living with HIV and are excited to open enrollment in our new Phase 3 clinical trials.”

Two new Phase 3 studies began enrolling participants this month:

- **MK-8591A-051** – A Phase 3, Randomized, Active-Controlled, Open-Label Clinical Study to Evaluate a Switch to Doravirine/Islatravir (DOR/ISL 100 mg/0.25 mg) Once-Daily in Participants With HIV-1 Who Are Virologically Suppressed on Antiretroviral Therapy
- **MK-8591A-052** – A Phase 3, Randomized, Active-Controlled, Double-Blind Clinical Study to Evaluate a Switch to Doravirine/Islatravir (DOR/ISL 100 mg/0.25 mg) Once-Daily in Participants With HIV-1 Who Are Virologically
The following new Phase 3 studies are expected to begin enrollment in March:

- **MK-8591A-P053** – A Phase 3, Randomized, Active-Controlled, Double-Blind Clinical Study to Evaluate the Antiretroviral Activity, Safety, and Tolerability of Doravirine/Islatravir (DOR/ISL 100 mg/0.25 mg) Once-Daily in HIV-1 Infected Treatment-Naïve Participants
- **MK-8591A-P054** – A Phase 3 Open-label Clinical Study of Doravirine/Islatravir (DOR/ISL [100 mg/0.25 mg]) Once-Daily for the Treatment of HIV-1 Infection in Participants Who Previously Received DOR/ISL (100 mg/0.75 mg) Once-Daily in a Phase 3 Clinical Study
  - Certain study participants currently enrolled in prior DOR/ISL studies (Protocols 018, 020 and 033), which evaluated once-daily DOR/ISL 100/0.75 mg in treatment-naïve and virologically suppressed participants, will have the option of transitioning to study P054 evaluating once-daily DOR/ISL 100/0.25 mg as a potential fixed-dose combination, two-drug regimen.

Select Merck abstracts for islatravir at the Conference on Retroviruses and Opportunistic Infections (CROI) 2023 include:

- Switch to DOR/ISL (100/0.75MG) QD From B/F/TAF: Week 48 Results From a Phase 3 Trial. Late-breaker oral presentation: 197. Mills, A, et al.
- Switch to DOR/ISL (100/0.75MG) QD: Week 48 Results From An Open-label Phase 3 Trial. Late-breaker oral presentation: 196. Molina, J-M, et al.

For more information, including details around the virtual programming, please visit the [CROI 2023 website](https://www.croi.org/).

**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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