Merck Highlights Commitment to HIV Research with Presentations for Investigational Anti-HIV Agent MK-8591 at IAS 2019

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Data Include Week 48 Results from Phase 2B Study Evaluating MK-8591 in Combination with Doravirine

KENILWORTH, N.J. -- (BUSINESS WIRE) -- Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced today that the results from studies evaluating MK-8591, an investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI), are scheduled to be presented at the International AIDS Society Conference on HIV Science (IAS 2019) taking place July 21 – 24, 2019 in Mexico City.

“Building upon our proud heritage in HIV, we are excited to share these latest findings for MK-8591,” said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. “Based upon the Phase 2B results to be presented at IAS 2019, our company plans to initiate Phase 3 trials evaluating MK-8591 with doravirine for the treatment of HIV-1.”

Abstracts to be presented at IAS 2019

- MK-8591, at doses of 0.25 to 2.25 mg QD, in combination with doravirine establishes and maintains viral suppression through 48 weeks in treatment-naïve adults with HIV-1 infection. Late-breaking Oral Presentation. Wednesday, July 24, 11:00-12:30 CDT. Abstract WEAB0402LB. J-M Molina et al.
- First-in-human trial of MK-8591-eluting implants demonstrates concentrations suitable for HIV prophylaxis for at least one year. Late-breaking Oral Presentation. Tuesday, July 23, 16:30-18:00 CDT. Abstract TUAC0401LB. R. Matthews et al.
- Tolerability, safety and efficacy of MK-8591 at doses of 0.25 to 2.25 mg QD, in combination with doravirine and lamivudine through 24 weeks in treatment-naïve adults with HIV-1 infection. Late-breaking Poster Presentation. Tuesday, July 23, 12:30-14:30 CDT. Abstract LBPED46. J-M Molina et al.

For more information, please visit the IAS 2019 website.

Doravirine is marketed as PIFELTRO® in the United States. PIFELTRO (doravirine, 100 mg) is a once-daily non-nucleoside reverse transcriptase inhibitor (NNRTI) to be administered in combination with other antiretroviral (ARV) medicines currently indicated for the treatment of HIV-1 infection in adult patients not previously treated with antiretroviral therapy. PIFELTRO was approved by the U.S. Food and Drug Administration (FDA) on August 30, 2018 to be administered in combination with other antiretrovirals for the treatment of HIV-1 infection in adult patients with no prior ARV treatment experience. A supplemental New Drug Application is under review by the FDA for use (in combination with other antiretrovirals) in people living with HIV-1 who are switching from a stable antiretroviral regimen and whose virus is suppressed (HIV-1 RNA <50 copies/mL). The Prescription Drug User Fee Act (PDUFA) date is Sept. 20, 2019.

Selected Safety Information about PIFELTRO (doravirine)

PIFELTRO 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 PIFELTRO plasma concentrations may occur, which may decrease the effectiveness of PIFELTRO. Immune reconstitution syndrome can occur, including the occurrence of autoimmune disorders with variable time to onset, which may necessitate further evaluation and treatment. Co-administration of PIFELTRO with efavirenz, etravirine or nevirapine is not recommended. If co-administered with rifabutin, increase PIFELTRO dosage to one tablet twice daily (approximately 12 hours apart).
Consult the full Prescribing Information prior to and during treatment for important potential drug-drug interactions. The safety of PIFELTRO is based on two studies, DRIVE-FORWARD and DRIVE-AHEAD. In DRIVE-FORWARD, the most common adverse reactions (incidence ≥5%, all intensities) were nausea (7%), headache (6%), fatigue (6%), diarrhea (5%) and abdominal pain (5%). In DRIVE-AHEAD, the most common adverse reactions (incidence ≥5%, all intensities) were dizziness (7%), abnormal dreams (5%) and nausea (5%).

There is a pregnancy exposure registry that monitors pregnancy outcomes in individuals exposed to PIFELTRO during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry at 1-800-258-4263. Mothers infected with HIV-1 should be instructed not to breastfeed if they are receiving PIFELTRO (doravirine) due to the potential for HIV-1 transmission.

About MK-8591

MK-8591 is Merck’s investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) currently being evaluated in clinical trials for the treatment of HIV-1 infection in combination with other antiretrovirals, as well as for pre-exposure prophylaxis of HIV-1 infection as a single investigational agent, across a variety of formulations.

Our Commitment to HIV

For more than 30 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.

About Merck

For more than a century, Merck, a leading global biopharmaceutical company 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. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer’s disease and infectious diseases including HIV and Ebola. 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 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 2018 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 PIFELTRO (doravirine) at: https://www.merck.com/product/usa/pi_circulars/p/pifeltro/pifeltro_pi.pdf; and Patient Information for PIFELTRO (doravirine) at: https://www.merck.com/product/usa/pi_circulars/p/pifeltro/pifeltro_ppi.pdf

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