Merck to Present New Data from Studies of Investigational HIV Therapies Doravirine and MK-8591 at CROI 2018

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KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that data from studies of Merck’s robust HIV pipeline, including doravirine, a late-stage investigational non-nucleoside reverse transcriptase inhibitor (NNRTI), and MK-8591, an investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI), a “first of its kind” mechanism to enter clinical trials, are scheduled to be presented at the Conference on Retroviruses and Opportunistic Infections (CROI 2018). In addition, Merck scientists will present data from experiments investigating the mechanisms of formation and maintenance of HIV reservoirs and the impact of HIV persistence in the gut on immune recovery during antiretroviral therapy. CROI 2018 is taking place in Boston, Massachusetts, from March 4-7, 2018.

“Merck’s commitment to HIV has never wavered, and we are very excited about the progress being made in our labs today to both better understand HIV and to bring forward the next generation of potential treatments,” said Dr. George Hanna, associate vice president, clinical research, Merck Research Laboratories.

Presentations include Week 48 subgroup analysis from the pivotal Phase 3 DRIVE-AHEAD trial evaluating the efficacy and safety of doravirine (DOR), lamivudine (3TC) and tenofovir disoproxil fumarate (TDF) in a once-daily fixed-dose combination single tablet as a complete regimen (DOR/3TC/TDF) for the treatment of HIV-1 infection in treatment-naïve adults. In addition, results from a Phase 1 study evaluating MK-8591, an investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) that potentially inhibits HIV reverse transcriptase through multiple mechanisms will be presented in a late breaking abstract session.

Merck Abstracts at CROI 2018:

- Abstract # 491: Similar Efficacy and Safety by Subgroup in DRIVE-AHEAD: DOR/3TC/TDF versus EFV/FTC/TDF
  - Chloe Orkin
  - Poster presentation, Monday, March 5, 2:30 – 4:00 PM, Poster Hall D
- Abstract # 89LB: Low Dose MK-8591 Protects Rhesus Macaques Against Rectal SHIV Infection
  - Martin Markowitz
  - Late-breaker oral presentation, Tuesday, March 6, 11:45 AM, Ballroom B
- Abstract # 26: Multiple Daily Doses of MK-8591 as Low as 0.25 mg Are Expected to Suppress HIV
  - Randolph P. Matthews
  - Oral presentation, Monday, March 5, 11:00 AM, Auditorium
- Abstract # 158: CD32+ CD4+ T Cells Are HIV Transcriptionally Active Rather Than a Resting Reservoir
  - Mohamed Abdel-Mohsen
• Oral presentation, Wednesday, March 7, 5:45 PM, Ballroom A
• Abstract # 730: Validation of a Chronic Kidney Disease Risk Score in HIV+ Patients in the US
  • Anthony Mills
• Poster presentation, Tuesday, March 6, 2:30 – 4:00 PM, Poster Hall D
• Abstract # 316: A Bispecific Approach for Targeting Negative Checkpoint Receptors in HIV-1 Latency
  • Daniel Gorman
• Poster presentation, Tuesday, March 6, 2:30 – 4:00 PM, Poster Hall A
• Abstract # 383: Higher Rectal p24 Levels Correlate with Poor CD4 Recovery in Treated HIV Infection
  • Bonnie J. Howell
• Poster presentation, Wednesday, March 7, 2:30 – 4:00 PM, Poster Hall A
• Abstract # 376: IL-10 Signaling Is a Key Mechanism of SIV Persistence in ART-Treated Rhesus Macaques
  • Maria Pino
• Poster presentation, Wednesday, March 7, 2:30 – 4:00 PM, Poster Hall A
• Abstract # 393: Blinded Evaluation of Ultrasensitive Assays of HIV in Plasma
  • Sheila M. Keating
• Poster presentation, Wednesday, March 7, 2:30 – 4:00 PM, Poster Hall A

About Doravirine

Doravirine (MK-1439, DOR) is an investigational NNRTI being evaluated by Merck for the treatment of HIV-1 infection. DOR is being evaluated in several ongoing clinical trials both as a once-daily single-entity tablet in combination with other antiretroviral agents in a tailored regimen, and as a once-daily fixed-dose combination (DOR/3TC/TDF) in a complete single tablet regimen. Phase 3 trials include DRIVE-FORWARD, a trial comparing DOR to once-daily ritonavir-boosted darunavir (DRV+r), each administered in combination with emtricitabine (FTC)/TDF or abacavir (ABC)/3TC, in treatment-naive adults; DRIVE-AHEAD, a trial comparing DOR/3TC/TDF to efavirenz (EFV)/FTC/TDF in treatment-naive adults; and DRIVE-SHIFT, a trial evaluating a switch to DOR/3TC/TDF in HIV-1 infected adults who are currently virologically suppressed on another antiretroviral regimen. Other ongoing Phase 2 clinical trials include an evaluation of DOR/3TC/TDF in treatment-naive adults with transmitted resistance to NNRTIs and in people switching from EFV due to intolerability.

Earlier this year, the U.S. Food and Drug Administration (FDA) accepted for review two New Drug Applications (NDAs) for DOR for the treatment of HIV-1 infection in treatment-naive adults. The submission includes a once-daily single-entity tablet in combination with other antiretroviral agents in a tailored regimen, and a once-daily fixed-dose combination (DOR/3TC/TDF) in a complete single tablet regimen. The FDA has set a target action date of October 23, 2018, for both applications.

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 infection. Preclinical evidence indicates that MK-8591 inhibits HIV reverse transcriptase through multiple mechanisms that are different from any approved anti-HIV medicines, including traditional nucleoside reverse transcriptase inhibitors (NRTIs). MK-8591 is being evaluated in a 3-part Phase 2b dose-ranging trial, DRIVE2SIMPLIFY, a study of MK-8591 in combination with doravirine.

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 2017 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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