



NEWS RELEASE

Merck Announces New Data from Broad HIV Program at CROI 2020

3/2/2020

KENILWORTH, N.J.--(**BUSINESS WIRE**)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced today the presentation of new data from its ongoing HIV research programs at the Conference on Retroviruses and Opportunistic Infections (CROI 2020) taking place March 8 – 11, 2020 in Boston, Massachusetts. At the conference, data from several studies will be shared, including an analysis of the efficacy of weekly oral doses of the investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) islatravir as postexposure prophylaxis (PEP) in the SIV/rhesus macaque IV challenge model; metabolic outcomes from a Phase 2b trial of islatravir with doravirine (100 mg) and lamivudine (3TC, 300 mg) or with a fixed dose combination of doravirine, 3TC and tenofovir disoproxil fumarate (TDF, 300 mg) in previously untreated adults; and ongoing research into ways to target HIV viral reservoirs. The islatravir as PEP study will be featured in an official CROI press conference.

“Merck’s commitment to HIV spans exploratory research to Phase 3 trials and is fueled by our goal to develop meaningful scientific innovations that someday may help people living with HIV,” said Dr. George Hanna, vice president and therapeutic area head of infectious diseases, Global Clinical Development, Merck Research Laboratories. “We look forward to discussing the latest evidence for the clinical potential of our investigational candidates, including islatravir.”

Select abstracts in the CROI 2020 program include:

- Weekly Oral Islatravir Provides Effective PEP Against IV Challenge with SIVmac251. Oral Presentation. Session 89 Late Breaker (Abstract 4468). M. Markowitz et al.
 - Discussion at official CROI press conference: Tuesday, March 10, 7:30 a.m., Room 210, Hynes

Convention Center

- Islatravir Metabolic Outcomes in Phase 2B Trial of Treatment-Naïve Adults with HIV-1. Poster Presentation. Session 686 (Abstract 1166). G. McComsey et al.
- MK-8504 and MK-8583 (Tenofovir Prodrugs) Single-Dose PK and Antiviral Activity in HIV Infection. Poster Presentation and Themed Discussion. Session 468 (Abstract 1066). R. Matthews et al.
- Distinct HIV Reservoir Measures Correlate with Defective But Not Intact Pro-Viral DNA. Poster Presentation. Session 309 (Abstract 2343). E. Papasavaset al.
- HIV Gag p24 Persists in Tissue and Correlates with Immune Response. Poster Presentation. Session 316 (Abstract 3388). P. Zuck et al.

For more information, please visit the **CROI 2020 website**.

Indications and Usage for PIFELTRO and DELSTRIGO

PIFELTRO is indicated in combination with other antiretroviral (ARV) agents for the treatment of HIV-1 infection in adult patients with no prior ARV treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable ARV regimen with no history of treatment failure and no known substitutions associated with resistance to doravirine.

DELSTRIGO is indicated as a complete regimen for the treatment of HIV-1 infection in adult patients with no prior ARV treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable ARV regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of DELSTRIGO.

Selected Safety Information about PIFELTRO and DELSTRIGO

Warning: Posttreatment Acute Exacerbation of Hepatitis B (HBV)

All patients with HIV-1 should be tested for the presence of HBV before initiating ARV therapy. Severe acute exacerbations of HBV have been reported in patients who are coinfecting with HIV-1 and HBV and have discontinued products containing lamivudine or tenofovir disoproxil fumarate (TDF), which are components of DELSTRIGO. Patients coinfecting with HIV-1 and HBV who discontinue DELSTRIGO should be monitored with both clinical and laboratory follow-up for at least several months after stopping DELSTRIGO. If appropriate, initiation of anti-HBV therapy may be warranted.

PIFELTRO and DELSTRIGO are 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 doravirine plasma concentrations may occur, which may decrease the effectiveness of DELSTRIGO and PIFELTRO.

DELSTRIGO is contraindicated in patients with a previous hypersensitivity reaction to lamivudine.

Renal impairment, including cases of acute renal failure and Fanconi syndrome, have been reported with the use of TDF. DELSTRIGO should be avoided with concurrent or recent use of a nephrotoxic agent (eg, high-dose or multiple NSAIDs). Cases of acute renal failure after initiation of high-dose or multiple NSAIDs have been reported in patients with risk factors for renal dysfunction who appeared stable on TDF.

Prior to or when initiating DELSTRIGO, and during treatment, assess serum creatinine, estimated creatinine clearance, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus. Discontinue DELSTRIGO in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome. Discontinue DELSTRIGO if estimated creatinine clearance declines below 50 mL/min.

In clinical trials in HIV-1 infected adults, TDF was associated with slightly greater decreases in bone mineral density (BMD) and increases in biochemical markers of bone metabolism. Serum parathyroid hormone levels and 1,25 Vitamin D levels were also higher. Cases of osteomalacia associated with proximal renal tubulopathy have been reported with the use of TDF.

Immune reconstitution syndrome can occur, including the occurrence of autoimmune disorders with variable time to onset, which may necessitate further evaluation and treatment.

Because DELSTRIGO is a complete regimen, co-administration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.

Co-administration of PIFELTRO with efavirenz, etravirine, or nevirapine is not recommended.

If DELSTRIGO is co-administered with rifabutin, take one tablet of DELSTRIGO once daily, followed by one tablet of doravirine (PIFELTRO) approximately 12 hours after the dose of DELSTRIGO.

If PIFELTRO is 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 more information on potential drug-drug interactions.

Because DELSTRIGO is a fixed-dose combination tablet and the dosage of lamivudine and TDF cannot be adjusted,

DELSTRIGO is not recommended in patients with estimated creatinine clearance less than 50 mL/min.

The most common adverse reactions with DELSTRIGO (incidence \geq 5%, all intensities) were dizziness (7%), nausea (5%), and abnormal dreams (5%). The most common adverse reactions with PIFELTRO (incidence \geq 5%, all intensities) were nausea (7%), dizziness (7%), headache (6%), fatigue (6%), diarrhea (6%), abdominal pain (5%), and abnormal dreams (5%).

The safety of DELSTRIGO in virologically-suppressed adults was based on Week 48 data from subjects in the DRIVE-SHIFT trial. Overall, the safety profile in virologically-suppressed adult subjects was similar to that in subjects with no ARV treatment history.

Serum ALT and AST Elevations: In the DRIVE-SHIFT trial, 22% and 16% of subjects in the immediate switch group experienced ALT and AST elevations greater than 1.25 X ULN, respectively, through 48 weeks on DELSTRIGO. For these ALT and AST elevations, no apparent patterns with regard to time to onset relative to switch were observed. One percent of subjects had ALT or AST elevations greater than 5 X ULN through 48 weeks on DELSTRIGO. The ALT and AST elevations were generally asymptomatic, and not associated with bilirubin elevations. In comparison, 4% and 4% of subjects in the delayed switch group experienced ALT and AST elevations of greater than 1.25 X ULN through 24 weeks on their baseline regimen.

There is a pregnancy exposure registry that monitors pregnancy outcomes in individuals exposed to PIFELTRO or DELSTRIGO during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263.

Mothers infected with HIV-1 should be instructed not to breastfeed if they are receiving PIFELTRO or DELSTRIGO due to the potential for HIV-1 transmission.

About Islatravir (MK-8591)

Islatravir 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 125 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 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 2019 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

Please see Prescribing Information for DELSTRIGO (doravirine/3TC/TDF) at:

https://www.merck.com/product/usa/pi_circulars/d/delstrigo/delstrigo_pi.pdf and Patient Information for DELSTRIGO (doravirine/3TC/TDF) at:

https://www.merck.com/product/usa/pi_circulars/d/delstrigo/delstrigo_ppi.pdf

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