



NEWS RELEASE

# Merck Presents Early Evidence on Extended Delivery of Investigational Anti-HIV-1 Agent Islatravir (MK-8591) via Subdermal Implant

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Phase 1 Data Presented Today at IAS 2019

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced today results from a Phase 1 study evaluating the pharmacokinetics and safety of a prototype subdermal drug-eluting implant for extended administration of islatravir, the company's investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI), in healthy volunteers. The early findings of this prototype were presented as a late-breaking oral presentation (Abstract TUAC0401LB) at the **10th International AIDS Society Conference on HIV Science** (IAS 2019) in Mexico City and featured in the official IAS 2019 press program.

"We are encouraged by the results of this proof of concept study exploring the potential of delivering meaningful doses of islatravir over a 12-week period," said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. "At Merck, we recognize multiple options are needed to address the needs of individuals at risk of HIV-1, and we are committed to investigating those options. Through the application of our established expertise in drug delivery, we are seeking to capture the potential of islatravir for HIV-1 pre-exposure prophylaxis (PrEP)."

Merck is conducting a broad development program to evaluate the potential of islatravir for the treatment and prevention of HIV-1 infection. The lead program in treatment of HIV-1 infection is assessing a once-daily, oral, 2-drug regimen. The company is also exploring several potential options for PrEP, including a drug-eluting implant, as noted above, and a once-monthly oral formulation. The investigational once-daily, 2-drug regimen for the

treatment of HIV-1 treatment will be presented as a late-breaking oral presentation tomorrow (July 24) and is in the official press program at the **IAS 2019**. For the once-monthly oral formulation for PrEP, Merck plans to initiate a Phase 2, double-blind, placebo-controlled study to evaluate the safety, tolerability, and pharmacokinetics of investigational oral islatravir once-monthly in participants at low- risk for HIV-1 infection (ClinicalTrials.gov: **NCT04003103**). The trial is due to commence recruitment in September 2019.

## Phase 1 Implant Study Results for Investigational Anti-HIV Agent Islatravir

The Phase 1 randomized, 2-panel, double-blind, placebo-controlled, adaptive design clinical trial evaluated the safety and pharmacokinetics of islatravir administered using a polymer drug eluting implant, approximately the size of a match (2mm by 4cm), in healthy adult volunteers. Participants were randomized to receive an implant containing islatravir at doses of either 62 mg (n=6), 54 mg (n=6) or placebo (n=4) that was inserted sub-dermally in the skin of the upper arm of the non-dominant hand. After 12 weeks the implant was removed, and participants were evaluated for a further 4 weeks.

Both implant doses resulted in intracellular concentrations of islatravir, as measured in peripheral blood mononuclear cells, that remained above calculated pharmacokinetic thresholds through 12 weeks. Based on subsequent modeling, the implant containing islatravir 62mg was estimated to deliver levels well above the threshold at 12 months (and even beyond), providing early evidence for its potential as a once-yearly option for PrEP. The results of the study also indicate that control of intracellular concentrations can be managed by varying the islatravir load in the implant.

In this study, there were no discontinuations due to adverse events (AE) and no severe implant-related AEs reported. All participants reported at least one AE and all drug-associated AEs were assessed to be mild or moderate in severity. The most common reported AEs occurred at the implant site and included hematoma (6/6; 6/6; 4/4), pain/tenderness (6/6; 3/6; 2/4), erythema (5/6; 2/6; 0/4), induration (6/6; 5/6; 0/4) and pruritus (5/6; 0/6; 1/4) for the 62mg; 54mg and placebo groups respectively. There were no clinically significant differences observed between islatravir and placebo groups in pooled analysis of vital signs, ECG parameters, and safety laboratory studies. No systemic drug associated effects were noted.

## About Islatravir

Islatravir (formerly 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 (PrEP) 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](http://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](http://www.sec.gov)).

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