NEWS RELEASE

Merck Advances Phase 3 Trial to Evaluate Investigational Islatravir as Once-Monthly Oral PrEP for Women at High Risk for Acquiring HIV-1

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Collaboration with the Bill & Melinda Gates Foundation Seeks to Bring Forward a New HIV Prevention Option to Help Address the HIV Epidemic with Focus on Women in Sub-Saharan Africa

KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced a collaboration with the Bill & Melinda Gates Foundation (the foundation) where the foundation is committing to provide funding to support a pivotal Phase 3 study investigating a once-monthly oral pre-exposure prophylaxis (PrEP)1 option in women and adolescent girls at high risk for acquiring HIV-1 infection in sub-Saharan Africa. The study, IMPOWER 22, will evaluate the efficacy and safety of islatravir -- Merck's novel investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) under evaluation for both treatment and prevention -- and is anticipated to begin by early 2021. More than half of new HIV infections globally occur in sub-Saharan Africa, with women accounting for nearly 60 percent of new infections in this region.

"Our collaboration with the Bill & Melinda Gates Foundation exemplifies our shared mission to end the global HIV epidemic through meaningful innovations in HIV prevention, including additional PrEP options," said Dr. Roy D. Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. "Islatravir is a promising antiviral candidate with evidence from ongoing clinical trials to support its development as a once-monthly oral PrEP agent. Through this collaboration, we can further explore the potential of islatravir as part of our work towards the collective global public health goal of reducing the number of new HIV infections."

“The world will not be able to end the HIV epidemic until we can effectively prevent HIV acquisition in at-risk individuals and populations,” said Dr. Emilio Emini, director of the TB & HIV program, the Bill & Melinda Gates Foundation. “This collaboration will help advance HIV science and potentially offer a new option to prevent HIV acquisition among at-risk women, both in sub-Saharan Africa and globally.”

Per the agreement between the foundation and Merck, the foundation, in its role as a funder, intends to provide grant funding to the International Clinical Research Center (ICRC) at the University of Washington Department of Global Health, which is collaborating with Merck on the IMPOWER 22 study. This grant will support ICRC’s work with experienced trial sites in sub-Saharan Africa to enroll, follow and retain the large number of women required for this research. Merck will be the trial sponsor, responsible for supplying the medicine, gaining regulatory and customs approvals, and providing operational expertise and resources for management of the trial, such as site monitoring and data reporting. Merck will be funding the IMPOWER 22 clinical trial in the United States.

“Globally, women continue to be underserved in HIV research and care. In 2019, women accounted for 48 percent of new infections, and in 2018, AIDS-related illnesses remained the leading cause of death for women during their reproductive years,” said Prof. Elizabeth Anne Bukusi, MBChB, PhD, senior principal clinical research scientist and co-director of the Research Care Training Program at the Center for Microbiology Research of The Kenya Medical Research Institute, and a trial investigator. “We will not turn the tide on HIV globally until we turn the tide on the virus in Africa, and this clinical trial seeks to help advance this effort through its focus on women, especially younger women, who remain disproportionately at risk on this continent.”

About IMPOWER Clinical Trials Program

IMPOWER 22is a randomized, active-controlled, double-blind, multisite Phase 3 study evaluating the efficacy and safety of islatravir administered orally once-monthly as PrEP in cisgender women who are at high risk for HIV-1 infection in sub-Saharan Africa and the United States. The active comparator for this study, emtricitabine/tenofovir disoproxil fumarate (FTC/TDF), will be administered orally once daily. Approximately 4,500 cisgender women and adolescent girls, ages 16 through 45, will be randomized (stratified by site and age) in a 1:1 ratio to receive either islatravir or FTC/TDF for the duration of the study. Information on this study will be posted shortly on **www.clinicaltrials.gov**.

Merck also plans to conduct additional studies in HIV prevention with islatravir in once-monthly oral PrEP. These studies will include IMPOWER 24, a global Phase 3 clinical trial to evaluate islatravir as a once-monthly oral agent for PrEP at sites across the world and among other key populations impacted by the epidemic, including men who have sex with men (MSM) and transgender women.

About Islatravir (MK-8591)

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. In 2012, Merck licensed islatravir (4′-ethynyl-2-fluoro-2′-deoxyadenosine or EFdA) from the Yamasa Corporation based in Choshi, Japan.

Merck's 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 the Bill & Melinda Gates Foundation

Guided by the belief that every life has equal value, the Bill & Melinda Gates Foundation works to help all people lead healthy, productive lives. In developing countries, it focuses on improving people's health and giving them the chance to lift themselves out of hunger and extreme poverty. In the United States, it seeks to ensure that all people —especially those with the fewest resources—have access to the opportunities they need to succeed in school and life. Based in Seattle, Washington, the foundation is led by CEO Mark Suzman, under the direction of Bill and Melinda Gates and Warren Buffett.

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 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 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**).

1 PrEP is a way for people who do not have HIV, who are considered high-risk for acquiring HIV, to prevent the infection. Currently, the only available/approved dosing option is to take a pill every day. PrEP has been shown to effectively reduce the risk of HIV infection from sex when taken daily, but is less effective if it is not taken consistently. (Source: **https://www.cdc.gov/hiv/risk/prep/index.html**)

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