Merck Launches Major Trial of Monthly Islatravir PrEP Pill for Women

The company also has plans to study monthly islatravir’s efficacy as HIV prevention among men who have sex with men.

November 16, 2020 By Benjamin Ryan

Partnering with the Bill & Melinda Gates Foundation, pharmaceutical giant Merck will launch a major, late-stage trial of a monthly pill form of the antiretroviral islatravir as pre-exposure prophylaxis (PrEP) against HIV among women and adolescent girls at risk for the virus.

The pharmaceutical company also has plans to launch a similar trial, called IMPOWER 24, among HIV-negative men who have sex with men and transgender women.

Formerly known as MK-8591, islatravir is an extremely potent experimental antiretroviral (ARV) that is also under investigation as a once-weekly HIV treatment and as an implant for prevention of the virus that could last as long as a year. It is the first drug in the nucleoside reverse transcriptase translocation inhibitor class of ARVs.

With funding support from the Gates Foundation, Merck is launching the randomized, active-controlled, double-blind, multisite Phase III IMPOWER 22 study of once-monthly oral islatravir as PrEP among HIV-negative, at-risk cisgender women and adolescent girls in sub-Saharan Africa and the United States.

The trial, which will enroll about 4,500 women and girls ages 16 to 45, is slated to begin in early 2021 and is expected to run for about three years.

The participants will be randomized evenly to receive either monthly islatravir or daily Truvada (tenofovir disoproxil fumarate/emtricitabine) as PrEP for the duration of the study, plus a placebo version of the opposing drug. This means that all the women will still be instructed to take a daily pill.

“The world will not be able to end the HIV epidemic until we can effectively prevent HIV acquisition in at-risk individuals and populations,” Emilio Emini, PhD, the director of the TB & HIV program at the Gates Foundation, said in a press release.
Emini was on the Merck research team that first developed successful combination ARV therapy in the mid-1990s. He recalls those experiences in How to Survive a Plague, the Oscar-nominated 2012 documentary about that pivotal time in the history of the HIV pandemic.

“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,” Emini added.

To read a press release about the study, click here.

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