



Once-Monthly PrEP Pill Shows Promise

Merck aims to move a once-monthly pill dubbed MK-8527 into Phase III clinical trials this year.

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A once-monthly pill dubbed MK-8527 holds promise for HIV pre-exposure prophylaxis (PrEP), according to a study presented at the International AIDS Society Conference on HIV Science. Much of the enthusiasm at the meeting focused on the recent approval of twice-yearly lenacapavir PrEP (Yeztugo), but long-acting injectables aren't for everyone. Some people dislike needles or prefer the simplicity of taking a pill, and an oral drug might be easier to roll out worldwide.

MK-8527, from Merck, is a novel nucleoside reverse transcriptase translocation inhibitor, a successor to islatravir. Ken Mayer, MD, of Fenway Health, presented findings from a Phase II trial that enrolled 350 adults in the United States, Israel and South Africa. They were randomly assigned to receive one of three doses of MK-8527 or a placebo every four weeks.

MK-8527 was well tolerated with a safety profile comparable to the placebo. There was “no meaningful change” in average CD4 T-cell or total lymphocyte counts like those that led to discontinuation of higher doses of islatravir, Mayer reported. Protective drug levels were achieved within 24 hours.

Merck aims to move MK-8527 into Phase III clinical trials this year. EXPrESSIVE-10 will enroll nearly 4,600 young women in Africa, while EXPrESSIVE-11 will enroll about 4,400 people—including gay men and transgender and nonbinary people—in 16 countries.

“Until now, long-acting PrEP has been synonymous with injectable formulations, and the oral alternative of monthly MK-8527 could represent a paradigm shift,” says Rebeca Plank, MD, MPH, of MSD Research Laboratories. “We envision that monthly oral dosing could transform PrEP delivery and implementation models.”