Weekly HIV Treatment and PrEP Pills on the Horizon

Oral HIV treatment options that allow for less frequent dosing may offer more flexibility and discretion.

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Modern antiretrovirals are highly effective, so picking a regimen often comes down to ease of use. For some people, long-acting injectables for treatment or pre-exposure prophylaxis (PrEP) are the answer. But others find it inconvenient to schedule injection appointments—or they simply don't want shots.

A once-weekly single-tablet regimen containing islatravir and lenacapavir could be the first oral HIV treatment that doesn't require daily pills. Islatravir is a nucleoside reverse transcriptase translocation inhibitor, and lenacapavir is the first HIV capsid inhibitor. A twice-yearly injectable formulation of lenacapavir is approved for the treatment of multidrug-resistant HIV (Sunlenca) and as a solo drug for PrEP (Yeztugo).

In June, Merck and Gilead Sciences announced that the experimental islatravir/lenacapavir pill maintained viral suppression in people with HIV who switched from Biktarvy (bictegravir/tenofovir alafenamide/emtricitabine) or another standard daily oral regimen. Detailed findings from the Phase III ISLEND-1 and ISLEND-2 trials were scheduled to be presented at the International AIDS Conference in late July, after POZ went to press.

"Innovative oral HIV treatment options that allow for less frequent dosing may make a meaningful difference in the lives of people living with the virus, potentially offering more flexibility and discretion," says Gilead senior vice president of clinical development Jared Baeten, MD, PhD.

Gilead is also positioning lenacapavir pills as a once-weekly prevention option. The company has not conducted separate clinical trials of oral lenacapavir for PrEP but rather is relying on the established effectiveness of injectable lenacapavir in the Phase III PURPOSE 1 and PURPOSE 2 studies. The Food and Drug Administration (FDA) is expected to decide on approval by early February 2027.

Further back in the pipeline, Merck is working on a once-monthly oral PrEP candidate dubbed MK-8527, a successor to islatravir. Two Phase III clinical trials testing MK-8527 in diverse populations, EXPrESSIVE-10 and EXPrESSIVE-11, are expected to be completed in the second half of 2027. Gilead's weekly PrEP pill will have a head start if it gets the FDA nod in February, but Merck's monthly pill could offer another attractive option if approved in 2028.

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