Prevention: Twice-Yearly PrEP

Twice-yearly PrEP could be available this summer pending Food and Drug Administration approval.

March 24, 2025 By Liz Highleyman

Twice-yearly lenacapavir pre-exposure prophylaxis (PrEP) could be available this summer pending Food and Drug Administration (FDA) approval. The target decision date is June 19, and preparations for the U.S. launch are “well underway,” according to Gilead Sciences. The PURPOSE 1 trial showed that lenacapavir PrEP was 100% effective for young cisgender women in Africa. Likewise, the PURPOSE 2 study showed that lenacapavir injections every six months reduced the risk of HIV acquisition by 96% for gay and bisexual men and gender-diverse people. In both trials, lenacapavir was safe and well tolerated. In December, Gilead said that it had completed New Drug Application (NDA) submissions for lenacapavir PrEP. It was granted an FDA breakthrough therapy designation and priority review status, intended to speed up regulatory review. Under the Prescription Drug User Fee Act, expedited therapies can be approved in as little as six months, but it is unclear how FDA reorganization and staff layoffs under the new presidential administration could affect the timeline.
