



Prevention: Once-Yearly PrEP

Researchers at Gilead Sciences are now working on once-yearly HIV prevention shots.

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As twice-yearly lenacapavir for pre-exposure prophylaxis (PrEP) nears approval, researchers at Gilead Sciences are now working on once-yearly HIV prevention shots. Twice-yearly lenacapavir PrEP was 100% effective for young cisgender women in the PURPOSE 1 trial, while PURPOSE 2 showed that lenacapavir injections every six months reduced the risk of HIV acquisition by 96% for gay and bisexual men and gender-diverse people. At the Conference on Retroviruses and Opportunistic Infections, researchers presented the first data from a Phase I trial of two once-yearly lenacapavir formulations administered via intramuscular injection. The study enrolled 40 healthy adults at low risk for HIV acquisition. Lenacapavir levels were even higher than those seen with twice-yearly injections, remaining above the 95% effective concentration for at least 56 weeks. The most common side effect was mild injection site pain. Gilead plans to start a Phase III trial of once-yearly lenacapavir PrEP later this year, bypassing intermediate Phase II trials. Data could be ready for Food and Drug Administration review in 2027.

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