Yeztugo PrEP Works Well for Young People

The efficacy, pharmacokinetics and safety of twice-yearly lenacapavir PrEP were similar among people under 25 and older study participants.

August 11, 2025 By Liz Highleyman

Twice-yearly lenacapavir pre-exposure prophylaxis (PrEP) can be a good option for teens and young adults, a group that often struggles with consistent adherence to daily prevention pills, according to research presented at the International AIDS Society Conference on HIV Science (IAS 2025) in Rwanda.

In June, the Food and Drug Administration approved lenacapavir PrEP (brand name Yeztugo) based on impressive data from the Phase III PURPOSE 1 and PURPOSE 2 studies. Lenacapavir, from Gilead Sciences, is an antiretroviral drug that blocks HIV replication. It is not a vaccine that trains the immune system to fight the virus, but after all traditional HIV vaccine candidates have failed in large trials to date, long-acting PrEP is the next best thing.

Results from PURPOSE 1 showed that twice-yearly lenacapavir PrEP was 100% effective for young cisgender women in South Africa and Uganda. The injections significantly reduced HIV incidence compared with the background incidence rate and were superior to daily Truvada pills (tenofovir disoproxil fumarate/emtricitabine).

PURPOSE 2 showed that lenacapavir injections every six months reduced the risk of HIV acquisition by 96% relative to background incidence and by 89% compared to Truvada for gay and bisexual men and gender-diverse people in the United States and six other countries. In both trials, lenacapavir was safe and generally well-tolerated.

At the IAS conference, Katherine Gill, MBChB, MPH, of the Desmond Tutu HIV Centre at the University of Cape Town in South Africa, presented an analysis of outcomes among young people enrolled in the two trials. All of the more than 5,300 participants in PURPOSE 1 were women ages 16 to 25, a group that bears the brunt of the HIV epidemic in sub-Saharan Africa. In PURPOSE 2, about a third of the study population was 16 to 25 years old.

Worldwide, adolescents and young adults have a higher likelihood of HIV acquisition compared with older age groups, accounting for around a quarter of new cases. In the United States, young

people ages 13 to 24 accounted for 18% of new HIV diagnoses in 2023, according to the Centers for Disease Control and Prevention. Although youth have generally not been proactively included in Phase III HIV prevention trials, Gilead made a point to enroll them in PURPOSE 1 and PURPOSE 2.

This analysis included 56 women ages 16 or 17 and 2,084 women ages 18 to 25 assigned to lenacapavir in PURPOSE 1 and three people ages 16 or 17 and 749 people ages 18 to 25 who received lenacapavir in PURPOSE 2. All but three of the PURPOSE 1 participants were Black, while PURPOSE 2 included people of diverse races and ethnicities.

Twice-yearly lenacapavir PrEP demonstrated high effectiveness for young people. There were zero new HIV acquisitions among those ages 16 to 25 in PURPOSE 1. In PURPOSE 2, the two people who seroconverted in the lenacapavir group—a transgender woman and a cisgender man—were both in this age group, but the vast majority of young participants remained free of HIV. In contrast, 55 PURPOSE 1 participants and nine PURPOSE 2 participants on daily oral PrEP seroconverted during the study.

There were no clinically relevant differences according to age in pharmacokinetics (PK), or how the drug is metabolized and distributed in the body. Safety was also similar for young people and older adults; most injection site reactions were mild to moderate.

“Twice-yearly subcutaneous lenacapavir had high efficacy, favorable safety and no clinically relevant PK differences in youth, supporting the potential of lenacapavir to address challenges with daily oral PrEP and help reduce new HIV infections among youth,” the study authors concluded.

“Certain groups—including pregnant and lactating women, adolescents and young people—are disproportionately affected by HIV, yet have long been underrepresented in HIV clinical trials,” Linda-Gail Bekker, MBChB, PhD, director of the Desmond Tutu HIV Centre, said in a Gilead news release. “The PURPOSE program set a new standard for innovative, intentional inclusion by ensuring we would have safety and efficacy data in these populations from the outset. The results not only show that Yeztugo provides strong protection against HIV and was well tolerated in these groups, but also highlight the critical need for PrEP options that reflect people’s preferences—reducing barriers to uptake and helping close persistent gaps in prevention.”

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