



PURPOSE

Prevention with PURPOSE

Protecting Young People From HIV: Lessons From the PURPOSE 1 and 2 Studies of Lenacapavir for PrEP

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This is a summary of a scientific presentation that was originally presented by Dr Katherine Gill at IAS 2025 (Efficacy, Safety, and Pharmacokinetics of Twice-Yearly Subcutaneous Lenacapavir for PrEP Among Adolescents and Young People in the Phase 3 Trials PURPOSE 1 and PURPOSE 2). This summary presents only selected data and is not intended to replace the full presentation. The intended audience for this summary is registered conference attendees.

*For a list of coauthors, please see the original presentation ([here](#))

See www.purposestudies.com for more information on the PURPOSE studies

Background

HIV prevention medication, known as PrEP, helps to lower the chances of someone getting HIV. Young people between the ages of 15 and 25 are at a higher risk of getting HIV and need better options for HIV prevention medication.

PrEP is mostly available as a tablet, taken by mouth (orally) and must be taken every day, which many young people find hard to do. Lenacapavir is a long-acting type of PrEP that is given as an injection 2 times a year (every 6 months).

Lenacapavir is a new medication for HIV prevention that works by targeting the capsid protein, which is needed for the HIV virus to replicate.

In the PURPOSE 1 and PURPOSE 2 studies, lenacapavir worked at preventing HIV in a wide range of people. It was also very safe for people who used it.

In this analysis, researchers looked at how well lenacapavir worked in young people from the PURPOSE 1 and PURPOSE 2 studies. They also looked at lenacapavir levels in the blood.

Why did researchers do this analysis?

Researchers wanted to know how well lenacapavir works to prevent HIV in young people.

Who took part in the study and how were the medications studied?

5345 women in **PURPOSE 1** tested negative for HIV and received 1 of 3 study drugs: an injection of lenacapavir 2 times a year, or a once-daily tablet of emtricitabine and tenofovir alafenamide (F/TAF) or tenofovir disoproxil fumarate (F/TDF).

3271 people in **PURPOSE 2** tested negative for HIV and received 1 of 2 study drugs: an injection of lenacapavir 2 times a year or a once-daily tablet of F/TDF. In both **PURPOSE 1** and **PURPOSE 2**, people were randomly assigned to each group, and neither the doctors nor the study participants knew which group participants were assigned to.

Study designs

PURPOSE 1

8094 women
tested for HIV



HIV negative



Living with HIV: These people were immediately referred to receive HIV care. The samples were used to calculate the background HIV rate.

Group 1
(2140 women)

Group 2
(2135 women)

Group 3
(1070 women)

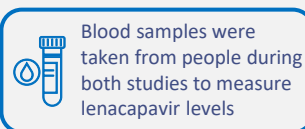
Week 0

Lenacapavir injections 2 times a year
(and F/TAF or F/TDF placebo* tablet daily)

F/TAF tablet once daily
(and lenacapavir placebo* injection 2 times a year)

F/TDF tablet once daily
(and lenacapavir placebo* injection 2 times a year)

12 months+



Blood samples were taken from people during both studies to measure lenacapavir levels

PURPOSE 2

4634 people
tested for HIV



HIV negative



Living with HIV: These people were immediately referred to receive HIV care. The samples were used to calculate the background HIV rate.

Group 1
(2183 people)

Group 2
(1088 people)

Week 0

Lenacapavir injections 2 times a year
(and F/TDF placebo* tablet daily)

F/TDF tablet once daily
(and lenacapavir placebo* injection 2 times a year)

12 months+

*Placebo tablets and injections contain an inactive substance and are not a medicine. They were used so that doctors and participants did not know which group participants were in.

In this analysis, young people were aged 16-25 years:



PURPOSE 1 (16-25 years)

< 18 years of age and ≥ 18 years of age

PURPOSE 2 (≥ 16 years)

≤ 25 years of age and > 25 years of age

What was measured?

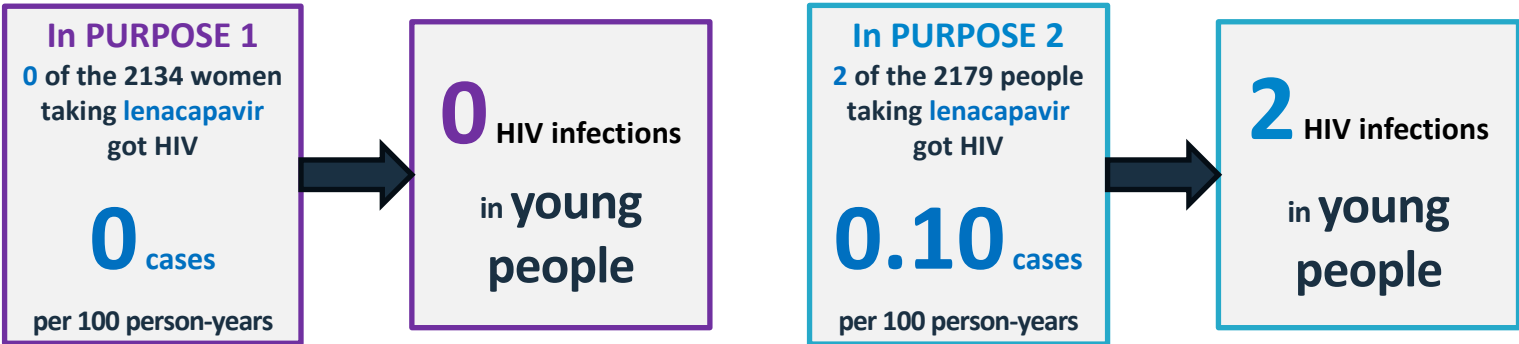
- Researchers measured the **number of people who acquired HIV** in each medication group
- Researchers looked at **whether lenacapavir was safe**
- Researchers **compared levels of lenacapavir in the blood** of young people and adults

See www.purposestudies.com for more information

A summary of PURPOSE 1 and PURPOSE 2, an analysis looking at how well lenacapavir works for HIV prevention in young people

What were the results?

Only 2 young people on lenacapavir got HIV



How safe was lenacapavir in young people?



Lenacapavir was safe and well tolerated in young people

- **Lenacapavir was safe and well tolerated** by young people, and only a few participants stopped taking lenacapavir because of side effects



- The most common side effects reported during this analysis were injection-site reactions, including **pain, redness, lump under the skin, thickening of skin, or swelling** at the site of the injection
- However, most injection-site reactions were mild, and only a few young people stopped taking lenacapavir because of injection-site reactions
- **The frequency and seriousness of injection-site reactions in young people was similar to that in adults in PURPOSE 1 and PURPOSE 2**

Did the levels of lenacapavir in the blood differ between young people and adults?



Lenacapavir levels in the blood were generally **similar in young people and adults**

Conclusions

- Lenacapavir was effective for HIV prevention in young people; only 2 young people taking lenacapavir got HIV
- Lenacapavir was safe and well tolerated in young people
- Blood lenacapavir levels were generally similar between young people and adults
- Lenacapavir injections 2 times a year work well and are safe in young people, making lenacapavir a good choice instead of daily tablets, potentially helping more young people use and stay on PrEP, and stop more young people from getting HIV

ACCESS: Please see the the full access statement [here](#).

Gilead believes working directly with generic manufacturers (voluntary licensing) is the fastest way to create broad and sustainable access to lenacapavir for PrEP for people who need it the most.

Reference: Gill K, et al. Oral OAC0503 presented at: IAS; July 13-17, 2025; Kigali, Rwanda

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