PURPOSE

Prevention with PURPOSE

Protecting Mothers and Babies From HIV: Lessons From the PURPOSE 1 Study of Lenacapavir for PrEP

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This is a summary of a scientific presentation that was originally presented by Dr. Linda-Gail Bekker at IAS 2025 (Inclusion of Pregnant and Lactating People in the PURPOSE 1 Study: Efficacy, Safety, and Pharmacokinetics). 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)

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Background

HIV prevention medication, known as PrEP, lowers the chances of someone getting HIV. People who are pregnant or breastfeeding are particularly vulnerable to getting HIV and need safe options to help prevent it. However, they are often not included in PrEP clinical studies.

Lenacapavir is a new long-acting HIV prevention medication. It is given as a shot (injection) just 2 times a year (once every 6 months). Studies in animals have shown no harmful effects of lenacapavir on the health of the baby.

The PURPOSE 1 study looked at how well lenacapavir worked to prevent HIV infection in cisgender women and whether it was safe. PURPOSE 1 was the first HIV prevention study to intentionally include pregnant and breastfeeding women.

In this analysis of PURPOSE 1, researchers aimed to find out whether lenacapavir can protect pregnant and breastfeeding people from getting HIV and if it is safe to use lenacapavir during pregnancy and breastfeeding. The researchers also looked at how lenacapavir moves through the body during and after pregnancy and checked whether the medicine passes into breast milk or affects the baby.

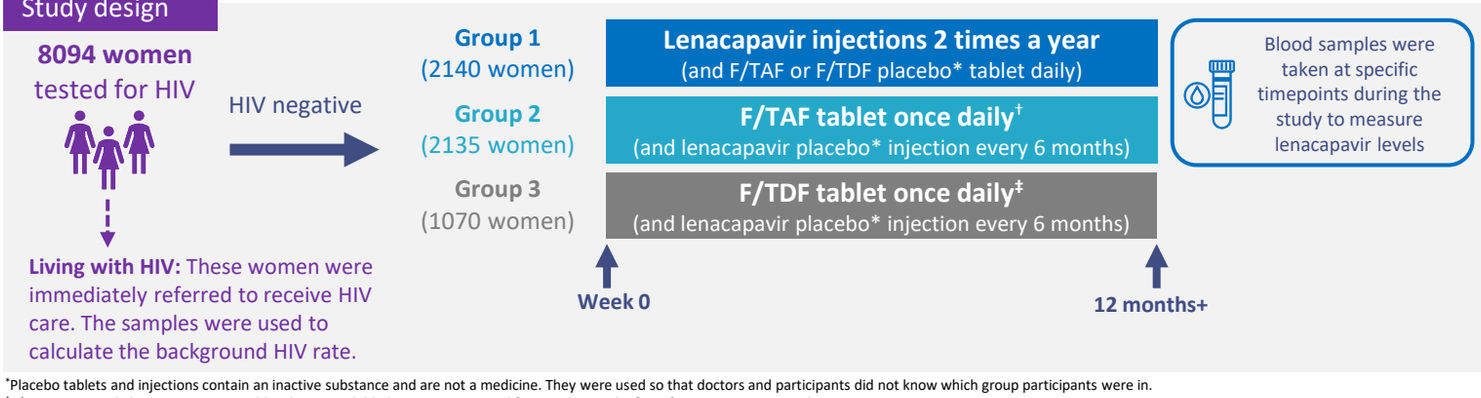
Why did researchers do this analysis?

Researchers wanted to know how well lenacapavir works to prevent HIV and how safe it is in pregnant and breastfeeding women in PURPOSE 1. They also wanted to know if the dose of lenacapavir should be changed during or after pregnancy.

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

5345 women 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). Women were randomly assigned to each group, and neither the doctors nor the study participants knew which group participants were assigned to.

Study design



*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.
†F/TAF is a once-daily HIV prevention tablet that is available but is not approved for people at risk of HIV from receptive vaginal sex.
‡F/TDF is the standard-of-care once-daily tablet used for HIV prevention.

Of the **5345** women included in the study:
- **487 became pregnant**
- In these 487 women, there were **509 confirmed pregnancies**

To respect women's choices about becoming pregnant, free contraception was offered during the PURPOSE 1 study but use of contraception was not required

Women who became pregnant could stay in the study if they agreed to do so

Women in the analysis were:

16-25‖ years of age

Characteristics were generally similar except:

Education level was generally higher in women who did not become pregnant

More women who became pregnant engaged in sex for financial or material benefits

‖One participant was 25 years of age when they entered the study but turned 26 years of age by the time they were assigned to a treatment group.

What was measured?

- Researchers described the **number of pregnant women who acquired HIV in each medication group**
- Researchers looked at whether **lenacapavir was safe** and the **outcomes of pregnancies**
- Researchers **compared levels of lenacapavir** in the blood of women who were pregnant or breastfeeding with those who were not, and they looked at the levels of lenacapavir in breast milk and in the blood of breastfed babies

We worked with communities, regulatory agencies, ethics committees, and maternal and children's health experts to responsibly include pregnant and breastfeeding women in PURPOSE 1

A summary of an analysis looking at lenacapavir for HIV prevention during pregnancy and breastfeeding in the PURPOSE 1 study

What were the results?

There were ZERO cases of HIV in women on lenacapavir who became pregnant during the study

184 out of 2140 women taking lenacapavir got pregnant
➔ **0 pregnant women got HIV**

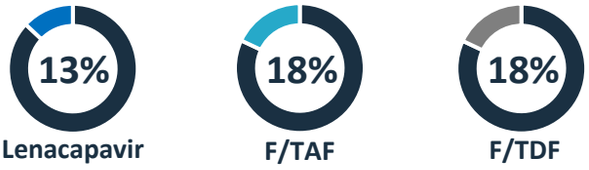
208 out of 2135 women taking F/TAF got pregnant
➔ **4 pregnant women got HIV**

95 out of 1070 women taking F/TDF got pregnant
➔ **1 pregnant woman got HIV**

None of the babies born to women who got HIV during the study had HIV

How did HIV prevention medication affect pregnancy outcomes?

Proportion of pregnancies ending in pregnancy loss, excluding elective abortions



- In pregnant women who received lenacapavir, the chances of losing the baby during pregnancy or birth (miscarriage/stillbirth) or of the baby having structural or functional differences at birth (congenital abnormalities) were similar to chances in the general population
- The chances were also similar between the different study treatments

- 10 babies were born with congenital abnormalities: 6 to women in the lenacapavir group and 4 to women in the F/TAF group
- All congenital abnormalities were within the expected background rates

How safe were HIV prevention medications during and after pregnancy?

Lenacapavir, F/TAF, and F/TDF were safe and well tolerated during pregnancy. Only one woman stopped taking lenacapavir because of side effects.

- Aside from injection-site reactions and spontaneous miscarriage, the most common side effects experienced by at least 10% of women who were pregnant or postpartum were **urinary tract infection, vaginal yeast infection, and upper respiratory tract infection**
- In total, **33% of women (44 out of 132) receiving lenacapavir** who received **at least one injection during or after pregnancy reported side effects of injection-site reactions**

Did the levels of lenacapavir in the blood of pregnant and breastfeeding women differ from lenacapavir levels in nonpregnant women?

Lenacapavir levels in the blood were **generally similar in pregnant, nonpregnant, and postpartum women**; therefore, pregnant women do not need different doses

Lenacapavir was found in breastmilk, but **levels in the blood of breastfed babies were very low**

Conclusions

- Zero pregnant or breastfeeding women receiving lenacapavir got HIV
- Lenacapavir was safe and well tolerated in pregnant and breastfeeding women, and pregnancy outcomes were similar to outcomes in the general population and in women receiving PrEP as tablets
- Blood levels of lenacapavir in pregnant and breastfeeding women were generally similar to levels in nonpregnant women; lenacapavir is transferred to breastmilk, but breastfed infants have very low levels of lenacapavir in their blood
- Active inclusion of pregnant and breastfeeding women in this study generated important results that support the use of lenacapavir for PrEP in pregnant and breastfeeding people

ACCESS: Please see 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.

References: Bekker L-G, et al. Oral OAC0504 presented at: IAS; July 13-17, 2025; Kigali, Rwanda

Acknowledgments: We extend our gratitude to the PURPOSE trial participants and their communities, our Global community advisory and accountability group, the site staff, and the investigators, and all the members of PURPOSE study team. This study was funded by Gilead Sciences, Inc. Medical writing support was provided by Aimee Sherlock, MSc (Aspire Scientific, UK) and was funded by Gilead Sciences, Inc.

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