PURPOSE

Prevention with PURPOSE

IAS 2025

Inclusion of Pregnant and Lactating People in the PURPOSE 1 Study: Efficacy, Safety, and Pharmacokinetics

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Acknowledgments and Presenter Disclosures

Acknowledgments

I want to begin my talk by extending my deepest gratitude to the PURPOSE trial participants who have shared their time, experiences, and bodies for the purposes of this research, and their families and communities, the global community advisory and accountability groups, the site staff and investigators, and the members of the PURPOSE study teams. Much of the fight against HIV and AIDS relies upon people living with HIV and people who want or need PrEP continuing to put themselves forward, and this research and our fight against HIV and AIDS is indebted to those past and present.

Disclosures

- Honoraria for advisories from Gilead Sciences, Inc., Merck Pty Ltd, and ViiV Healthcare; research grants to Desmond Tutu Health Foundation to conduct implementation science obtained from Johnson & Johnson and ViiV healthcare; served on the data safety monitoring board for the PrEPVACC HIV Vaccine trial
- Gilead Sciences, Inc., funded the study and designed the study with input from the PIs and G-CAG. The PIs and study staff gathered data; Gilead Sciences, Inc., monitored conduct of the trial, received the data, and performed analyses. The PURPOSE 1 Study Team all vouch for the data and analysis
- Medical writing support was provided by Aimee Sherlock, MSc (Aspire Scientific Ltd, UK), and was funded by Gilead Sciences, Inc.

G-CAG, Global Community Advisory Group; **PI**, principal investigator; **PrEP**, pre-exposure prophylaxis.

Summary

What is your main question?

- Is twice-yearly LEN for PrEP efficacious and safe during pregnancy and lactation?
- Are the blood levels of LEN during pregnancy and postpartum different compared with those in non-pregnant women?
- Is LEN present in breastfed infants?

What did you find?

- LEN was highly efficacious in pregnant and lactating people, with zero participants acquiring HIV
- LEN was safe and well tolerated in pregnant and lactating people. Pregnant and lactating people receiving LEN had similar pregnancy outcomes to the general population and to participants receiving oral PrEP
- Blood levels of LEN in pregnant and postpartum people were generally similar compared with those in nonpregnant people; LEN is transferred to breastmilk, but breastfed infants have very low levels of LEN in their blood

Why is it important?

- Proactively including pregnant and lactating people in PURPOSE 1 yielded valuable data about blood levels of LEN and safety, which support the use of LEN for PrEP in this important population

To access a copy of this presentation, please scan the QR code*

LEN, lenacapavir; **PrEP**, pre-exposure prophylaxis.

PURPOSE: First to Include Pregnant and Lactating People in Phase 3 HIV PrEP Trials

Pregnant and lactating people are disproportionately vulnerable to HIV-1 acquisition but **historically excluded** from Phase 3 HIV trials,[1,2] despite an **urgent unmet need** for HIV prevention options

LEN is a **first-in-class**, multistage HIV-1 capsid inhibitor with **high potency** and a **long half-life**, supporting **twice-yearly SC injection**[3,4]

Preclinical studies **do not indicate harmful effects of LEN** on fertility, pregnancy, fetal development, or postnatal development[4]

We evaluated the efficacy, safety, and PK of twice-yearly SC LEN for HIV prevention in pregnant and lactating people in PURPOSE 1

Middle image from: https://www.impaactnetwork.org/who-and-impaact-call-action-webinar-world-aids-day, reproduced with permission; © WHO, IMPAACT, CIPHER (2021). Right image from: https://www.hivpregnancyethics.org/, reproduced under a CC BY-NC 4.0 license. **LEN**, lenacapavir; **PK**, pharmacokinetics; **PrEP**, pre-exposure prophylaxis; **SC**, subcutaneous. 1. Drake AL, et al. *PLoS Med*. 2014;11:e1001608. 2.Davey DLJ, et al. *Lancet HIV*. 2022;9(3):e214-e222. 3. Link JO, et al. *Nature*. 2020;584:614-18. 4. Sunlenca USPI. Gilead Sciences, Inc. December 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215973s000lbl.pdf (accessed May 13, 2025).

PURPOSE 1: Developing a New Model for Ethical and Inclusive Study Design for Pregnant and Lactating People

KEY STAKEHOLDERS

- We engaged investigators and site staff, community stakeholders, regulatory agencies, ethics committees, and maternal/pediatric health experts to responsibly include pregnant and lactating people in PURPOSE 1

CONTRACEPTION

- To respect autonomy and reproductive choice, free contraception was offered during the study but not required

INCLUSION

- Participants who became pregnant could remain in the study after reconsent (fathers were also given the option to consent for their unborn infants)
- PURPOSE 1 implemented all WHO and IMPAACT toolkit recommendations for the inclusion of pregnant and lactating people[1]

IMPAACT, International Maternal Pediatric Adolescent AIDS Clinical Trials Network; **WHO**, World Health Organization.

1. WHO and IMPAACT Network. https://iris.who.int/bitstream/handle/10665/349842/9789240040182-eng.pdf?sequence=1 (accessed June 4, 2025).

PURPOSE 1 Study Design

Randomized Blinded Cohort

Participants randomized to LEN received loading doses of two 300-mg tablets of LEN on each of Days 1 and 2; participants randomized to F/TAF or F/TDF received matched placebos

Cross-Sectional Incidence Cohort

Cisgender women[a]

Not on PrEP, no HIV testing in the past 3 months, negative pregnancy test

- **HIV-negative test and eligible**[b]
- **HIV-positive test → recency assay used to estimate background HIV incidence**

2 **LEN SC every 26 weeks** — n = 2134[c]
+ oral F/TAF placebo or F/TDF placebo (2:1)

2 **F/TAF oral daily** — n = 2136[c]
+ SC LEN placebo every 26 weeks

1 **F/TDF oral daily** — Active control — n = 1068[c]
+ SC LEN placebo every 26 weeks

Background HIV incidence[d] **(n = 8094)**

Prespecified Interim Analysis[e]

50% of participants completed ≥ 52 weeks

Primary analysis[f]**:**
1. LEN vs background HIV
2. F/TAF vs background HIV

Secondary analysis[g]**:**
1. LEN vs F/TDF
2. F/TAF vs F/TDF

ClinicalTrials.gov: NCT04994509

[a]First participant screened August 2021; 50th-percentile participant randomized May 2023; last participant randomized September 2023. [b]Eligibility criteria included: body weight ≥ 35 kg, eGFR ≥ 60 mL/min, not pregnant. [c]n numbers represent the full analysis set for efficacy analyses. [d]Background HIV incidence is the incidence expected without PrEP that would have been expected in a placebo group (the counterfactual HIV incidence). [e]Because the randomized blinded phase was stopped early due to an efficacy outcome, the interim analysis served as the primary analysis. [f]IRR was assessed using a Wald test or likelihood ratio test if there were zero infections. [g]IRR was assessed using Poisson regression or an exact conditional Poisson regression model in case of zero infections.

eGFR, estimated glomerular filtration rate; **F/TAF**, emtricitabine/tenofovir alafenamide; **F/TDF**, emtricitabine/tenofovir disoproxil fumarate; **IRR**, incidence rate ratio; **LEN**, lenacapavir; **PrEP**, pre-exposure prophylaxis; **SC**, subcutaneous.

Bekker LG, et al. *N Engl J Med.* 2024;391:1179-92.

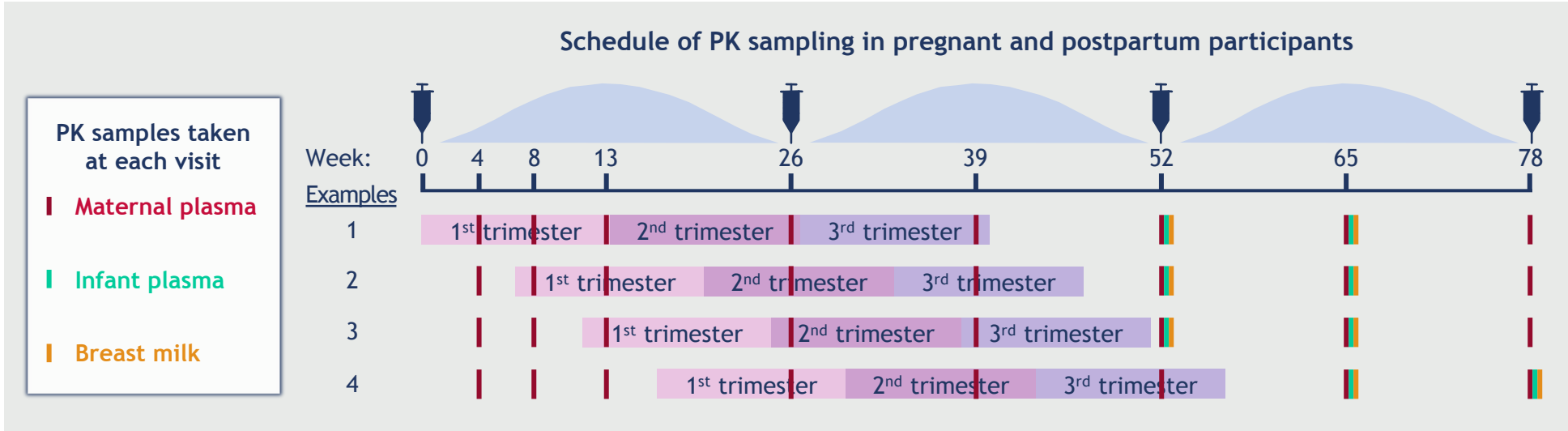
Nested PK Sub-Study: Designed to Limit Burden on Pregnant and Lactating Participants and their Infants

Pregnancy, Breast Milk, and Infant PK Sub-Study

Includes people who became pregnant while receiving LEN, and their infants

PK samples taken at each visit

- Maternal plasma
- Infant plasma
- Breast milk



- **Objectives:** To describe maternal systemic drug concentrations during pregnancy and postpartum and assess drug concentrations in breast milk and infants, while limiting visit burden for participants

EGA, estimated gestational age; **LEN**, lenacapavir; **PK**, pharmacokinetics.

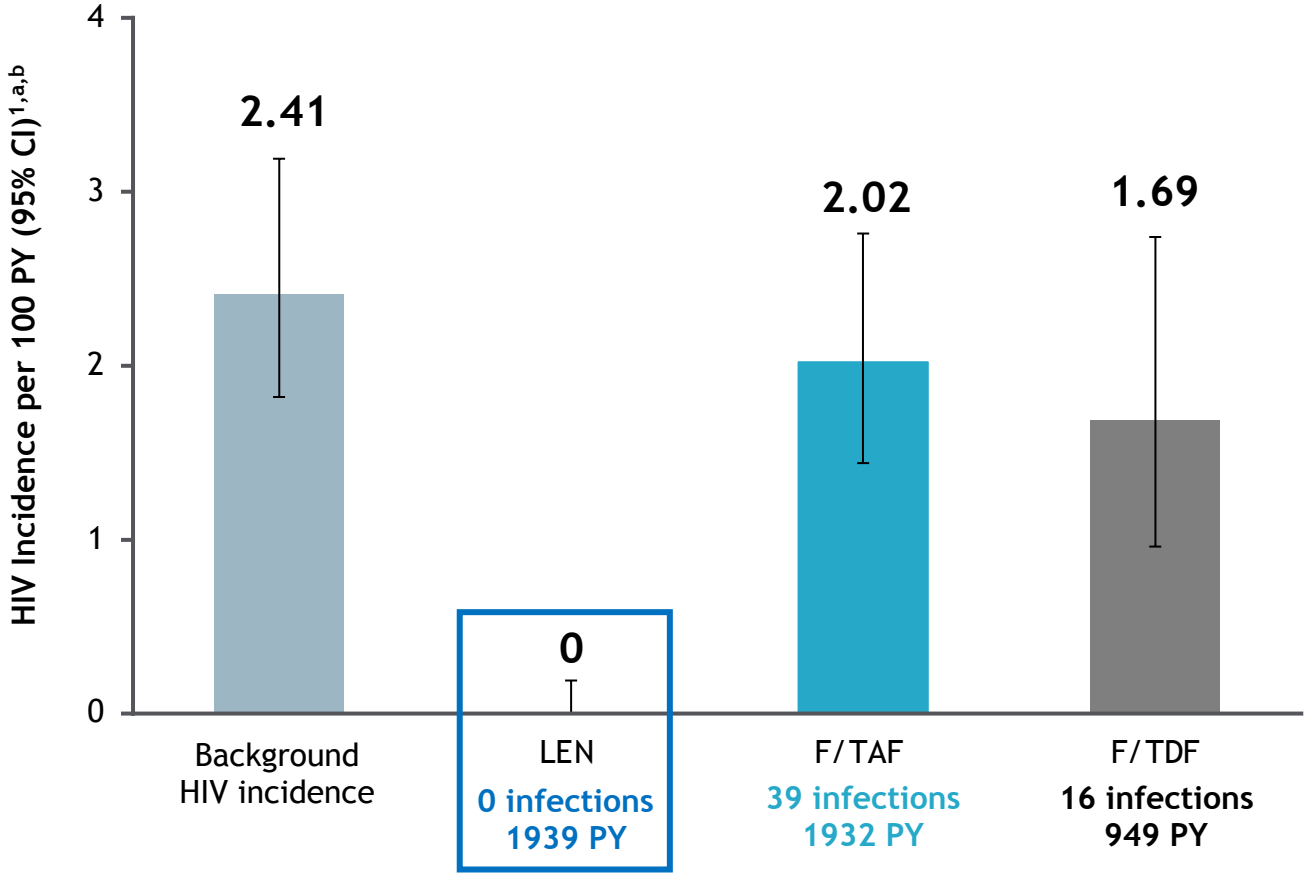
Baseline Demographics and Characteristics

Characteristic	LEN, n = 2140		F/TAF, n = 2135		F/TDF, n = 1070	
	Pregnancy, n = 184	No Pregnancy, n = 1956	Pregnancy, n = 208	No Pregnancy, n = 1927	Pregnancy, n = 95	No Pregnancy, n = 975
Age, years, median (range)[b]	21 (17-25)	21 (16-25)	22 (16-25)	21 (16-26)	21 (17-25)	21 (16-25)
Age 16 to < 18 years, n (%)	3 (1.6)	53 (2.7)	2 (1.0)	43 (2.2)	1 (1.1)	22 (2.3)
Black race,[c] n (%)	184 (100)	1953 (99.8)	207 (99.5)	1927 (100)	95 (100)	973 (99.8)
Some or no primary school, n (%)	46 (25.0)	140 (7.2)	41 (19.7)	133 (6.9)	20 (21.1)	56 (5.7)
Marital status, n (%)						
Married	6 (3.3)	20 (1.0)	7 (3.4)	23 (1.2)	2 (2.1)	15 (1.5)
Living with primary partner, n (%)	21 (11.4)	127 (6.5)	13 (6.3)	119 (6.2)	5 (5.3)	68 (7.0)
Any *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis*, or Syphilis, n (%)	63 (34.2)	664 (33.9)	72 (34.6)	702 (36.4)	40 (42.1)	333 (34.2)
Any prior use of PrEP, n (%)	10 (5.4)	133 (6.8)	10 (4.8)	114 (5.9)	5 (5.3)	66 (6.8)
Any prior HIV testing, n (%)	145 (78.8)	1570 (80.3)	169 (81.3)	1562 (81.1)	77 (81.1)	783 (80.3)
Modified VOICE risk score, median (Q1, Q3)	6.0 (5.0, 7.0)	7.0 (5.0, 7.0)	7.0 (6.0, 7.0)	7.0 (5.0, 7.0)	7.0 (6.0, 7.0)	7.0 (5.0, 7.0)
Intercourse for financial or material support in past 3 months, n (%)	76 (41.8)	417 (21.6)	79 (38.5)	424 (22.3)	44 (47.3)	207 (21.5)

487 participants with 509 pregnancies included[1]
Baseline demographics and characteristics were similar regardless of pregnancy or study arm

Participants with ≥ 1 confirmed pregnancy during the RBP primary analysis versus those with no reported pregnancies. Missing data and participants who preferred not to answer are excluded.
[a]Age on first study drug dose date. [c]All non-Black participants were multiracial. **F/TAF,** emtricitabine/tenofovir alafenamide; **F/TDF,** emtricitabine/tenofovir disoproxil fumarate; **LEN,** lenacapavir; **PrEP,** pre-exposure prophylaxis; **Q,** quartile; **RBP,** randomized blinded phase. 1. Bekker L-G, et al. *N Engl J Med*. 2024;391:1179-92.

Zero HIV Infections in Women Receiving LEN in PURPOSE 1



Five incident HIV infections in participants with pregnancies:

- 0/184 on LEN
- 4/208 on F/TAF
- 1/95 on F/TDF

No cases of vertical transmission

[a]Overall n: background HIV incidence group, 8094; LEN, 2134; F/TAF, 2136; F/TDF, 1068. [b]95% CIs: background HIV incidence group, 1.82-3.19; LEN, 0-0.19; F/TAF, 1.44-2.76; F/TDF, 0.96-2.74.
F/TAF, emtricitabine/tenofovir alafenamide; **F/TDF**, emtricitabine/tenofovir disoproxil fumarate; **LEN**, lenacapavir; **PY**, person-years.

Bekker L-G, et al. *N Engl J Med*. 2024;391:1179-92.

Pregnancy Outcomes Were Similar to Expected Rates in the Population

Participants and Pregnancies[1]	LEN n = 193	F/TAF n = 218	F/TDF n = 98
Confirmed pregnancies	193	218	98
Participants with confirmed pregnancy(ies)[a]	184	208	95
Pregnancy status, n (%)			
Completed	186 (96.4)	207 (95.0)	97 (99.0)
Unknown	7 (3.6)	11 (5.0)	1 (1.0)
Live births, n (%)[b]	128 (66.3)	119 (54.6)	56 (57.1)
Pregnancy losses, n (%)	60 (31.1)	89 (40.8)	41 (41.8)
Stillbirth[c]	5 (2.6)	6 (2.8)	3 (3.1)
Induced abortion	35 (18.1)	50 (22.9)	23 (23.5)
Spontaneous miscarriage[d]	20 (10.4)	33 (15.1)	15 (15.3)

- In total, 10 congenital abnormalities were reported (six in LEN arm; four in F/TAF arm)[e]

Expected spontaneous miscarriage rate[2,3]:

- **~10-20% of clinically recognized pregnancies**
- **~30% of biochemically detected pregnancies**

The incidence of congenital anomalies was within the expected background rate[4,5]

Pregnancy outcomes were similar to those expected for the population[5] and balanced across study arms

Analyses limited to pregnancies diagnosed while on RBP-assigned study drug and diagnosed prior to May 8, 2024 (data cutoff for RBP primary analysis). Denominator = number of confirmed pregnancies. Pregnancy outcomes included for all pregnancies, including outcomes that occurred after switch to open-label phases. [a]Some participants had >1 pregnancy. [b]Live birth data include three pregnancies that have two outcomes due to twins. [c]Fetal death occurring at ≥ 20 weeks' gestation. [d]Spontaneous miscarriage occurring at < 20 weeks' gestation. [e]Congenital abnormalities reported in LEN arm: congenital hemangioma (n = 1), umbilical hernia (n = 1), left hand polydactyly (n = 1), perimembranous ventricular septal defect (n = 1), congenital ventricular septal defect (n = 1), congenital reducible umbilical hernia (n = 1); in F/TAF arm: infant bilateral hydrocele (n = 1), right inguinal hernia and umbilical hernia, neonatal jaundice (n = 1), Down syndrome (n = 1), clubfoot (n = 1).
F/TAF, emtricitabine/tenofovir alafenamide; **F/TDF**, emtricitabine/tenofovir disoproxil fumarate; **LEN**, lenacapavir; **RBP**, randomized blinded phase. 1. Bekker L-G, et al. *N Engl J Med*. 2024;391:1179-92. 2. ACOG Committee on Practice Bulletins—Gynecology. *Obstet Gynecol*. 2018;132:e197-207. 3. Wilcox AJ, et al. *N Engl J Med*. 1988;319:189-94. 4. Mugo NR, et al. *JAMA*. 2014;312:362-71. 5. Makanani B, et al. *J Acquir Immune Defic Syndr*. 2018;79:566-72.

LEN is Safe and Well Tolerated During Pregnancy and Postpartum

Participants,[a,b] n (%)	LEN n = 184	F/TAF n = 208	F/TDF n = 95
Any adverse events during pregnancy and postpartum	135 (73.4)	142 (68.3)	68 (71.6)
Grade ≥ 2	112 (60.9)	112 (53.8)	55 (57.9)
Grade ≥ 3	36 (19.6)	39 (18.8)	22 (23.2)
Serious adverse events	41 (22.3)	50 (24.0)	22 (23.2)
Adverse events leading to discontinuation of study drug	1 (0.5)[c]	0	0
Adverse events during pregnancy and postpartum occurring in ≥ 10% of participants in any group[d]			
Urinary tract infection	39 (21.2)	34 (16.3)	27 (28.4)
Vulvovaginal candidiasis	17 (9.2)	22 (10.6)	8 (8.4)
Upper respiratory tract infection	20 (10.9)	16 (7.7)	6 (6.3)

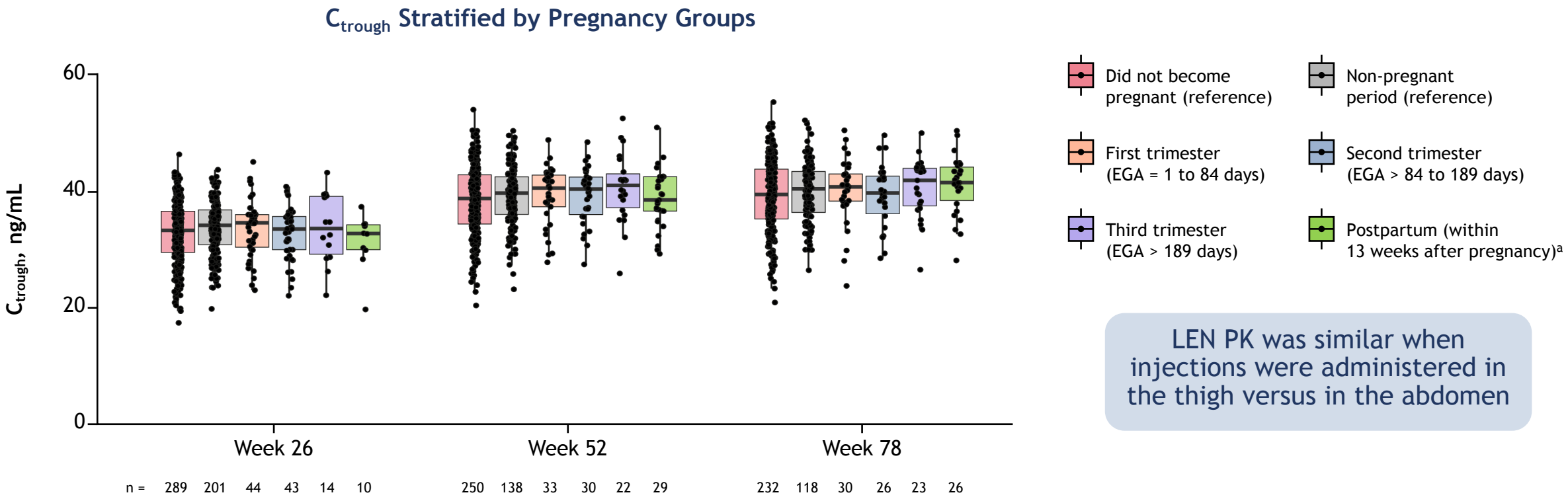
- Of participants who received at least one LEN injection during pregnancy/postpartum, 33.3% (44/132) reported ISRs to study SC injection (all Grade 1 or 2 in severity); the most common ISRs were nodules (26.5%; n = 35) and injection-site pain (12.9%; n = 17)

Adverse events were generally consistent with prior LEN, F/TAF, and F/TDF trials[1-3]

These analyses are limited to confirmed pregnancies included in the RBP primary analysis (data cutoff: May 8, 2024). Adverse events coded according to Medical Dictionary for Regulatory Activities Version 27.1 and graded by the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, Version 2.1. [a]Limited to adverse events occurring during the RBP with onset from last menstrual period date to pregnancy outcome date + 6 weeks. [b]ISRs to non-study medications are included but ISRs to study SC injection are excluded. [c]Discontinuation due to spontaneous miscarriage. [d]Spontaneous miscarriages have been excluded. **F/TAF**, emtricitabine/tenofovir alafenamide; **F/TDF**, emtricitabine/tenofovir disoproxil fumarate; **ISR**, injection site reaction; **LEN**, lenacapavir; **RBP**, randomized blinded phase; **SC**, subcutaneous. 1. Ogbuagu O, et al. *Lancet HIV*. 2023;10:e497-505. 2. Mayer KH, et al. *Lancet*. 2020;396:239-54. 3. Baeten JM, et al. *N Engl J Med*. 2012;367:399-410.

LEN Exposures Were Similar in Pregnant People Versus Non-Pregnant People

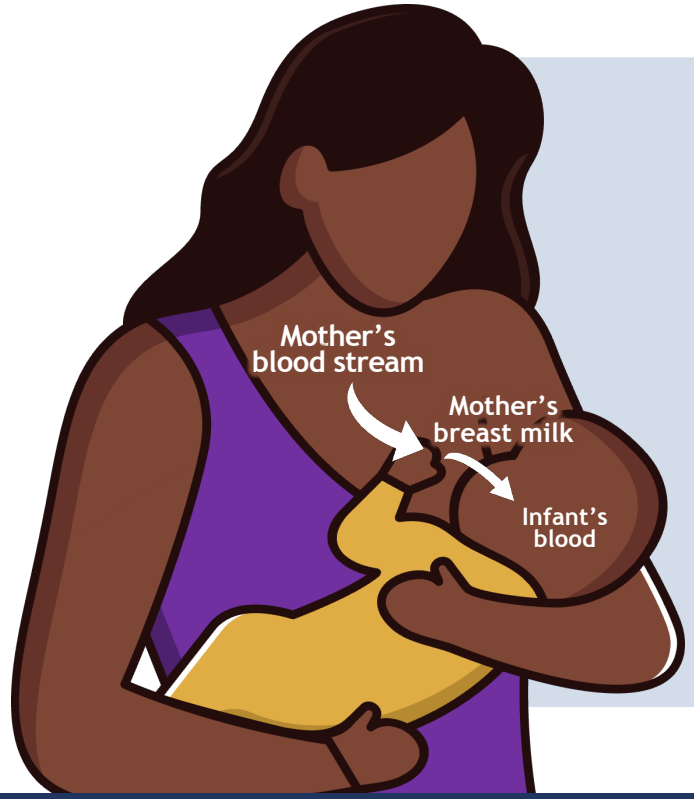
Across Week 26, Week 52, and Week 78 combined, a total of 107 first trimester, 99 second trimester, 59 third trimester, and 65 postpartum model-derived C_{trough} data were available



LEN PK was similar when injections were administered in the thigh versus in the abdomen

Box plots present model-derived C_{trough}. C_{max} showed a similar trend. Bottom and top of boxes represent Q1 and Q3, respectively; horizontal lines within boxes represent medians; whiskers represent ± 1.5 IQR. The population includes participants with available PK samples up to March 27, 2025. Pregnant people received thigh and/or abdomen injections. Model-derived LEN C_{trough} values following on-time complete injections were included. On-time complete injection was defined as both injections administered in full dose within ± 2 weeks of the target day relative to previous injection. Model-derived C_{trough} values were based on simulated concentration-time profiles for each participant. Concentration-time profiles were only simulated up to 26 weeks following the last on-time complete injection or the start of oral bridging or oral reloading, whichever came first. [a]Following childbirth or early pregnancy termination. **C_{max}**, maximum concentration; **C_{trough}**, trough concentration; **EGA**, estimated gestational age; **IQR**, interquartile range; **LEN**, lenacapavir; **PK**, pharmacokinetics; **Q**, quartile.

Minimal Exposure to LEN Observed in Breastfed Infants



- Median (Q1, Q3) **breastmilk-to-mother plasma ratio was 0.52** (0.38, 0.77) in 102 matched breast milk–mother pairs[a]
- Median (Q1, Q3) **breastfed-infant-to-mother plasma ratio was 0.02** (0.01, 0.05) in 98 matched mother-infant pairs[b]

LEN was present in breastmilk, but LEN concentrations were very low in breastfed infants

[a]Population limited to participants in the LEN PK breast-milk analysis set who received SC LEN in the RBP and became pregnant in RBP; ratio was calculated if the breast milk and plasma from the mother were collected at the same visit. [b]Population limited to participants in the LEN PK infant analysis set where the mother received SC LEN in RBP and became pregnant in RBP; ratio was calculated if plasma from the infant and mother was collected at the same visit. **LEN**, lenacapavir; **PK**, pharmacokinetics; **Q**, quartile; **RBP**, randomized blinded phase.

Conclusions

- PURPOSE 1 sets a new paradigm for ethical and inclusive trial design to accelerate data availability to support new PrEP options for pregnant and lactating people
- Twice-yearly LEN was efficacious, safe, and well tolerated in pregnant and lactating people
- No dose adjustment is required in pregnancy or post-partum
- 95% of eligible participants chose to continue or initiate LEN in the open-label extension, including participants who became pregnant during the RBP
- LEN for PrEP use in pregnancy supported in the US FDA label[1] and 2025 WHO Guidelines[2]

Proactive inclusion of pregnant and lactating women in PURPOSE 1 supports early adoption of LEN for PrEP in pregnant and lactating people

FDA, Food and Drug Administration, **LEN**, lenacapavir; **PK**, pharmacokinetics; **PrEP**, pre-exposure prophylaxis; **RBP**, randomized blinded phase; **WHO**, World Health Organization.

1. Gilead Sciences. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/220020s000lbl.pdf (accessed July 15, 2025). 2. Word Health Organization. Guidelines on lenacapavir for HIV prevention and testing strategies for long-acting injectable pre-exposure prophylaxis. July 14, 2025 (https://www.who.int/publications/i/item/9789240111608)

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PURPOSE 1 Study Team

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Accelerating Access for Global HIV Prevention

Expansive licensing	Rapid technology transfer	Simultaneous submissions
Earliest and geographically broadest (120 countries) voluntary licensing strategy ever for an antiretroviral	Agreements with 6 generics & full technology transfer within 3 months; Global Fund 2 million people for 3 years	US Approval June 2025 EU, EUM4All, South Africa, Brazil, Canada, Australia, Switzerland & more coming
Expediting Regulatory Review	**WHO endorsement**	**Manufacturing readiness**
EU-M4all application enables faster reviews in low- and middle-income countries	Guidelines released July 14, 2025 & prequalification later this year will facilitate global adoption	Gilead-supplied no-profit product & partnership agreements, bridging to sustainable generic supply

Collaborative implementation science studies to inform sustainable access, eg South Africa (Project PrEP, UNITAID/Wits RHI; ALIGN, Gates Foundation/Desmond Tutu Health Foundation) and Brazil (ImPrEP, IUNITAID/Fiocruz)