PURPOSE

Prevention with PURPOSE

HIV DRUG THERAPY GLASGOW 2024

Twice-Yearly Lenacapavir PrEP in Cisgender Gay, Bisexual, and Other Men, Transgender Women and Men, and Gender-Diverse People (PURPOSE 2)

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Disclosures

- Research grant obtained from NIAID
- Advisory boards for Gilead Sciences, and ViiV Healthcare
- Member of the Department of Health and Human Services panel for HIV treatment guidelines for adolescents
- Gilead Sciences 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 2 Study Team all vouch for the data and analysis
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G-CAG, Global Community Advisory Group; **NIAID**, National Institute of Allergy and Infectious Diseases; **PI**, principal investigator.

Populations Disproportionately Affected by HIV Incidence Need New HIV Prevention Choices

The uptake of, adherence to, and persistence on oral PrEP remains suboptimal in many populations who are disproportionately affected by HIV incidence[1-7]

We need to develop new PrEP 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[8,9]

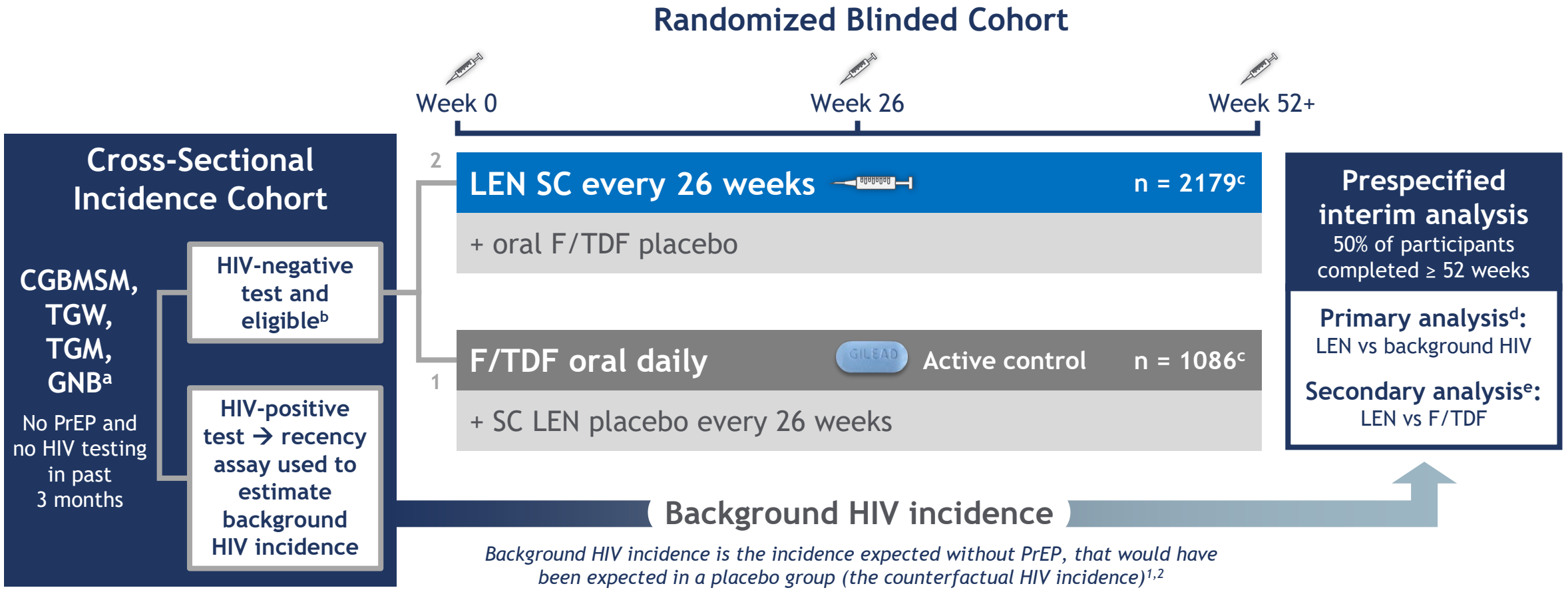
Injectable PrEP options have shown promise in overcoming barriers to adherence[10,11]

In the recent Phase 3 PURPOSE 1 trial, LEN was demonstrated to be highly efficacious and well tolerated for HIV prevention in cisgender women[12]

We evaluated the safety and efficacy of twice-yearly SC LEN for HIV prevention in cisgender gay, bisexual, and other men; transgender women; transgender men; and gender nonbinary individuals - who have sex with partners assigned male sex at birth

HIV, human immunodeficiency virus; **LEN**, lenacapavir; **PrEP**, pre-exposure prophylaxis; **SC**, subcutaneous. 1. Klein H, Washington TA. *J Gay Lesbian Soc Serv*. 2020;32:99-114. 2. Baral SD, et al. *Lancet Infect Dis*. 2013;13:214-22. 3. Kanny D, et al. *MMWR Morb Mortal Wkly Rep*. 2019;68:801-6. 4. Poteat T, et al. *J Acquir Immune Defic Syndr*. 2016;72(suppl 3):S210-9. 5. Sullivan PS, et al. *J Int AIDS Soc*. 2020;23:e25461. 6. Torres TS, et al. *Lancet Reg Health Am*. 2023;28:100642. 7. CDC HIV Surveillance Supplemental Report 2023. https://stacks.cdc.gov/view/cdc/156513 (accessed October 24, 2024). 8. Segal-Maurer S, et al. *N Engl J Med*. 2022;386:1793-803. 9. Link JO, et al. *Nature*. 2020;584:614-18. 10. Landovitz RJ, et al. *N Engl J Med*. 2021;385:595-608. 11. Delany-Moretlwe S, et al. *Lancet*. 2022;399:1779-89. 12. Bekker L-G, et al. *N Engl J Med*. 2024;391:1179-92.

PURPOSE 2 Study Design



ClinicalTrials.gov: NCT04925752

All participants had real-time HIV testing with an FDA-approved, rapid, point-of-care, fourth-generation antigen-antibody test and a central laboratory fourth-generation antigen-antibody test, which, if positive, was confirmed by an HIV-1/2 antibody differentiation assay, and, if the results were discrepant, a qualitative HIV RNA test was conducted. All participants also had a quantitative HIV-1 RNA test (Roche Cobas 6800 HIV-1 test) during screening (lower limit of quantification, 20 copies/mL). HIV-1 cases were defined as participants with ≥ 1 of the following laboratory results: positive HIV-1/2 differentiation assay, positive HIV-1 RNA qualitative test, or HIV-1 RNA quantitative test ≥ 200 copies/mL. On Days 1 and 2, all participants received a loading dose of 600 mg oral LEN or matched oral placebo. [a]The first participant was screened in June 2021, the 50th percentile participant was randomized in August 2023, and the last participant was randomized in December 2023. [b]Eligibility criteria included: age ≥ 16 years, weight ≥ 35 kg, eGFR ≥ 60 mL/min, not pregnant. [c]n numbers represent the full analysis set for efficacy analyses. [d]IRR was assessed using a Wald test.[1,2] [e]IRR was assessed using Poisson regression. **CGBMSM**, cisgender gay and bisexual men who have sex with men; **eGFR**, estimated glomerular filtration rate; **FDA**, US Food & Drug Administration; **F/TDF**, emtricitabine/tenofovir disoproxil fumarate; **GNB**, gender nonbinary individuals; **IRR**, incidence rate ratio; **TGM**, transgender men; **TGW**, transgender women. 1. Gao F, et al. *Stat Commun Infect Dis*. 2021;13:20200009. 2. Shao Y, Gao F. *Stat Commun Infect Dis*. 2024;16:20230004.

Assessments

Screening/baseline HIV testing

- Real-time HIV testing with FDA-approved, rapid, point-of-care fourth-generation Ag/Ab test and central laboratory fourth-generation Ag/Ab test, which, if positive, was confirmed by an HIV-1/2 Ab differentiation assay. If results were discrepant, qualitative HIV RNA test was conducted
- Quantitative HIV-1 RNA test also performed during screening, baseline, and if participants were > 28 weeks from prior injection

Follow-up visit HIV testing (W4, 8, 13, then Q13W)

- Real-time, rapid, point-of-care and central laboratory fourth-generation Ag/Ab tests with same confirmation procedures
- Plasma for LEN PK, retrospective RNA testing, and DBS for TFV-DP were stored at each visit

HIV Adjudication Committee

- A blinded adjudication panel reviewed all positive HIV testing results to determine HIV status and earliest visit with evidence of HIV

LEN adherence evaluated by on-time injection

- Defined as injection receipt within 28 weeks of prior injection

F/TDF adherence evaluated using TFV-DP level

- In DBS in a representative, preselected 10% of participants

LEN plasma concentrations evaluated

- In a representative, randomly preselected 10% of participants

HIV seroconversions

- LEN PK, DBS retrospective RNA testing, resistance testing
  - Genotypic HIV resistance testing of the capsid and protease/reverse transcriptase regions of the *gag* and *pol* genes was performed for those who acquired HIV

[a]Every visit: vitals and weight, AEs, HIV testing (rapid fourth-generation & central CDC algorithm), safety laboratory tests (chemistry, hematology, liver function tests, creatinine kinase, urine), urine pregnancy testing; baseline and every 26 weeks: metabolic testing (fasting lipids and glucose) and STI testing (gonorrhea, chlamydia, trichomonas vaginalis, syphilis).

Ab, antibody; **AE**, adverse event; **Ag**, antigen; **BL**, baseline; **CDC**, Centers for Disease Control and Prevention; **DBS**, dried blood spot; **PK**, pharmacokinetics; **Q13W**, every 13 weeks; **Scr**, screening; **STI**, sexually transmitted infection; **TFV-DP**, tenofovir-diphosphate; **W**, week.

Baseline Characteristics

Characteristic	LEN, n = 2183	F/TDF, n = 1088
Age, years, median (range)	28 (17-74)	29 (17-73)
Age 16 to ≤ 25, years, n (%)	752 (34.4)	344 (31.6)
Non-White race,[a] n (%)	1453 (66.8)	742 (68.3)
Hispanic/Latine ethnicity,[b] n (%)	1378 (63.2)	675 (62.0)
Highest education level college/university,[c] n (%)	1105 (50.6)	574 (52.9)
Gender identity, n (%)		
Cisgender man	1697 (77.7)	846 (77.8)
Gender diverse	486 (22.3)	242 (22.2)
STIs, n (%)		
Chlamydia trachomatis or *Neisseria gonorrhoeae*[d,e]	391 (17.9)	217 (19.9)
Syphilis	84 (3.8)	43 (4.0)
No prior HIV test, n (%)	597 (27.3)	306 (28.1)
Any prior lifetime use of PrEP, n (%)	515 (23.6)	249 (22.9)
Self-reported use of stimulants with sex in last 12 weeks, n (%)	491 (22.5)	271 (24.9)

Participants

Brazil 35.6%

US 20.6%

Peru 13.7%

Thailand 11.9%

South Africa 10.9%

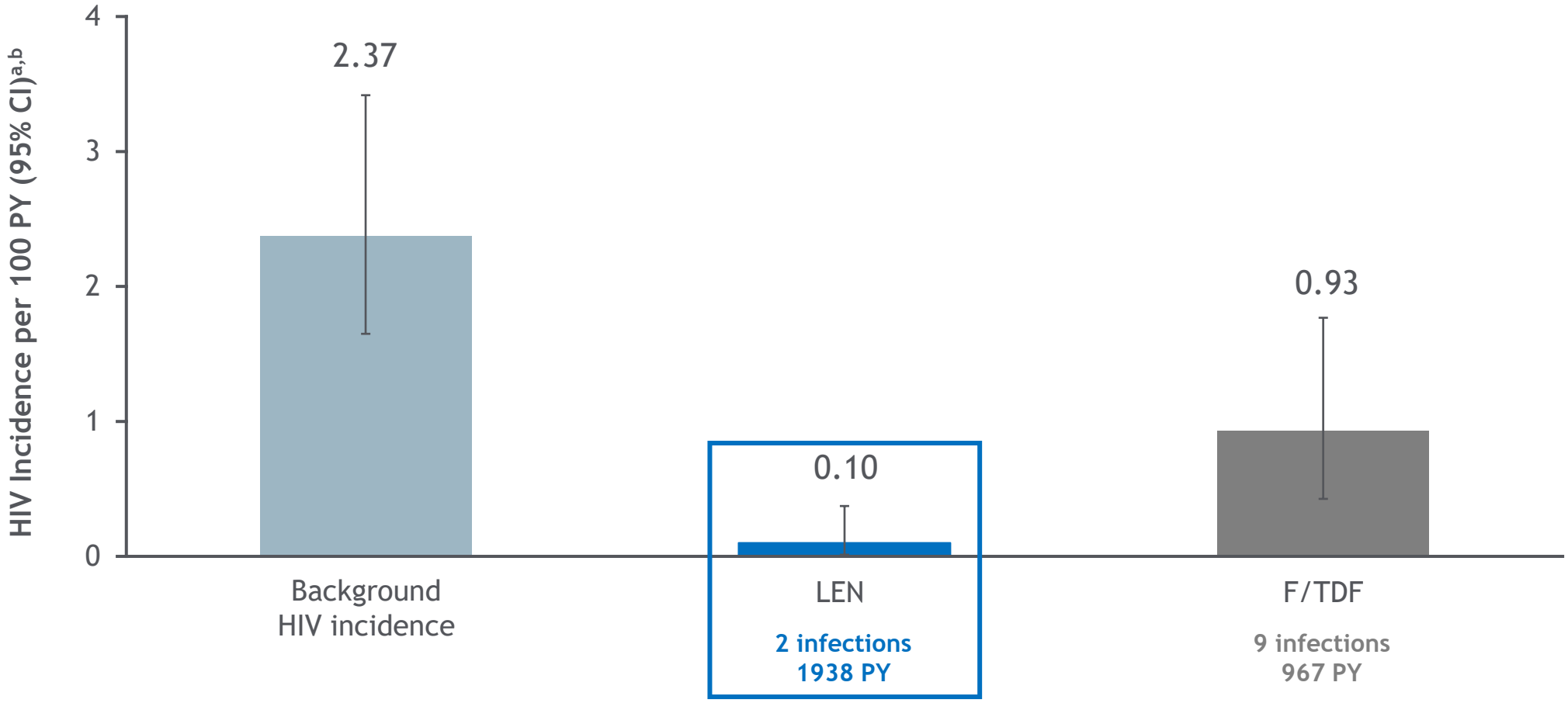
Argentina 6.9%

Mexico 0.4%

Participants were globally, racially, ethnically, and gender diverse; aged 17 to 74 years
Participants reported significant chemsex and STIs at baseline

Six participants were subsequently determined to have had HIV infection at the time of randomization, and thus 3265 were included in the modified ITT efficacy analysis. Unavailable or missing data were excluded from the calculation of percentage. [a]Race data were unavailable for eight participants in the LEN group and two participants in the F/TDF group. [b]Ethnicity data were unavailable for one participant in the LEN group. [c]Education level data were unavailable for one participant in the LEN group and two participants in the F/TDF group. [d]Testing for *T. vaginalis* was also performed at investigator discretion for participants assigned female at birth (1 case of *T. vaginalis* diagnosed at baseline in the LEN group). [e]Diagnoses for chlamydia or gonorrhea were based on rectal, pharyngeal, and urine testing at a central laboratory. **ITT,** intention-to-treat; **US**, United States.

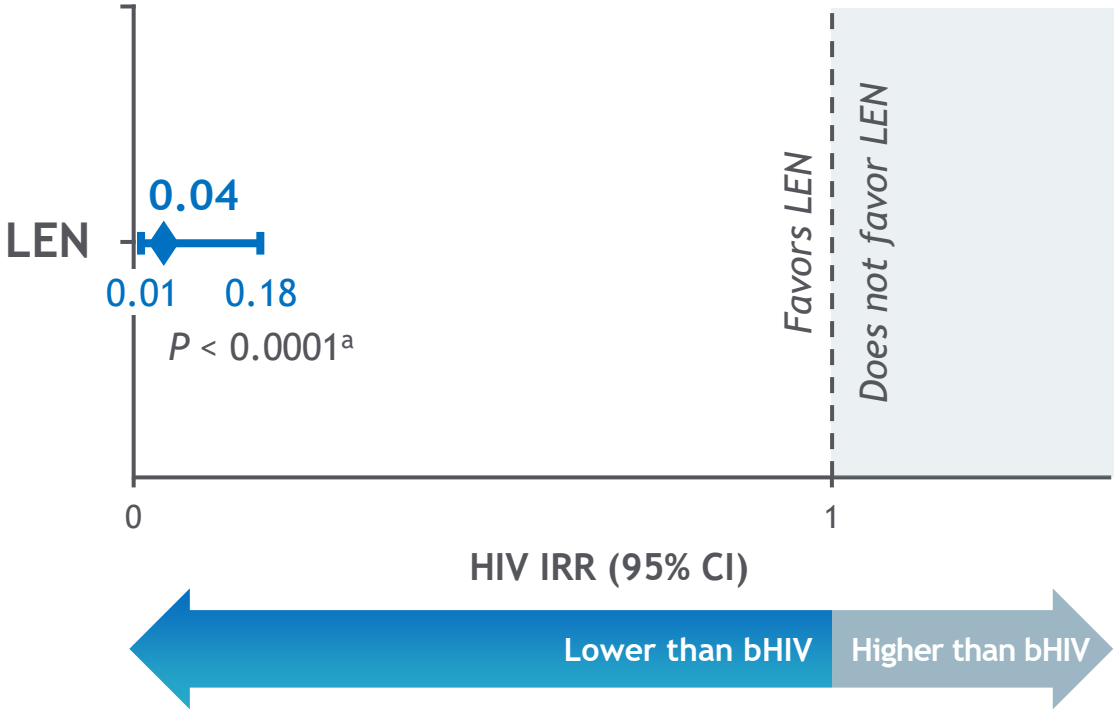
Very Low HIV Incidence in Participants Receiving LEN



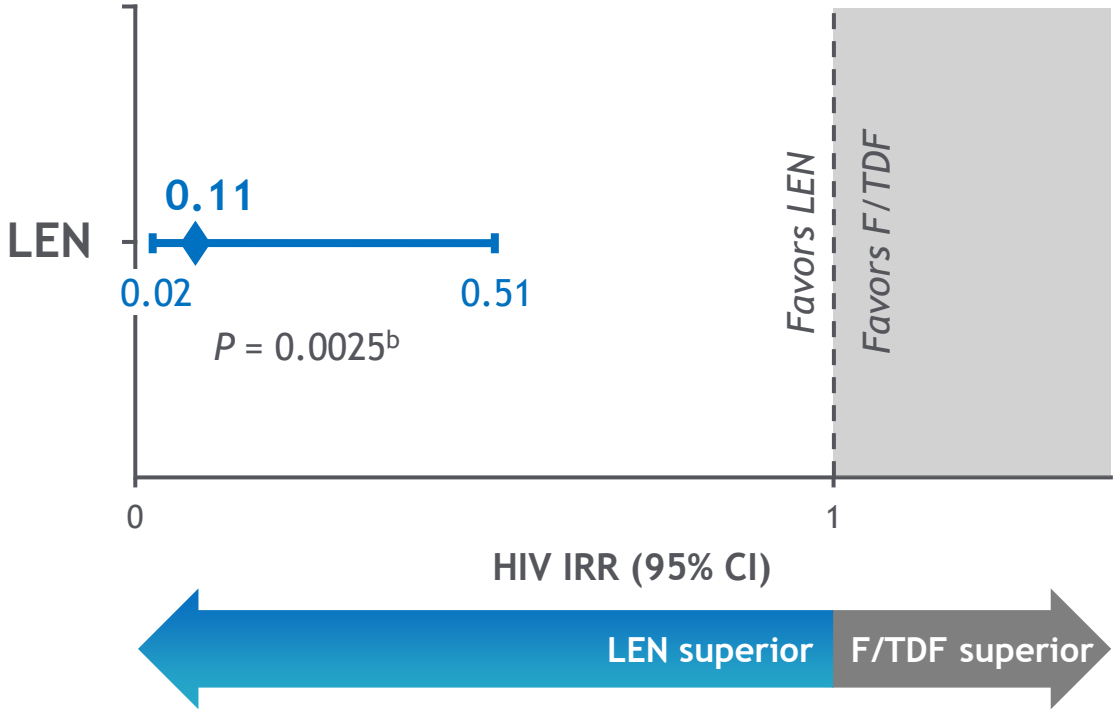
Median follow-up: 39.4 weeks

[a]Overall n: background HIV incidence group, 4634; LEN, 2179; F/TDF, 1086. [b]95% CIs: background HIV incidence group, 1.649-3.417; LEN, 0.012-0.373; F/TDF, 0.426-1.768.
CI, confidence interval; **PY**, person-years.

Primary Analysis:
LEN Superior to bHIV Incidence



Secondary Analysis:
LEN Superior to F/TDF



LEN reduced HIV infections by 96% compared with background HIV incidence and by 89% compared with daily oral F/TDF

[a]HIV IRR vs background HIV was assessed using a Wald test.[1] [b]HIV IRR vs F/TDF was assessed using Poisson regression.
bHIV, background HIV incidence.

1. Gao F, et al. *Stat Commun Infect Dis*. 2021;13:20200009.

Adherence to LEN Injections Was High and Consistent Adherence to F/TDF Was High but Declined Over Time

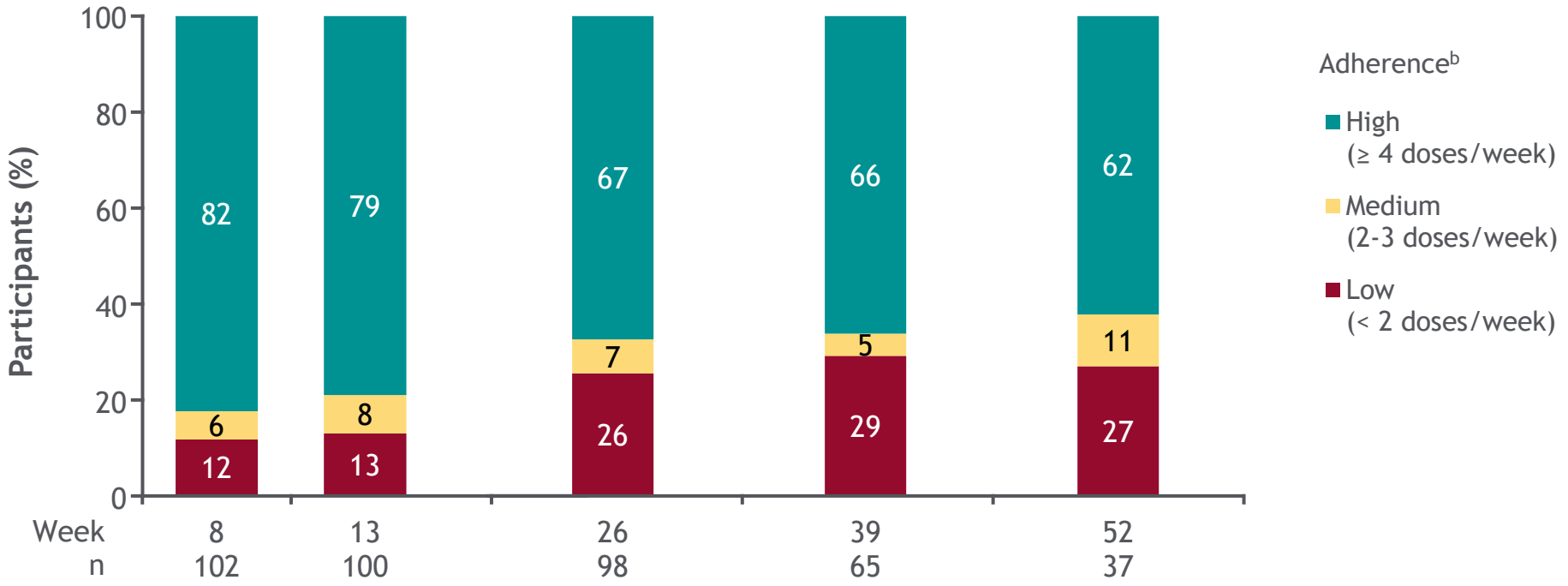
Injection Adherence

LEN injections were on time for:[a]

- 90% (1729/1912) at Week 26
- 93% (678/727) at Week 52

On-time injection rate was similar for LEN and placebo (F/TDF) injections

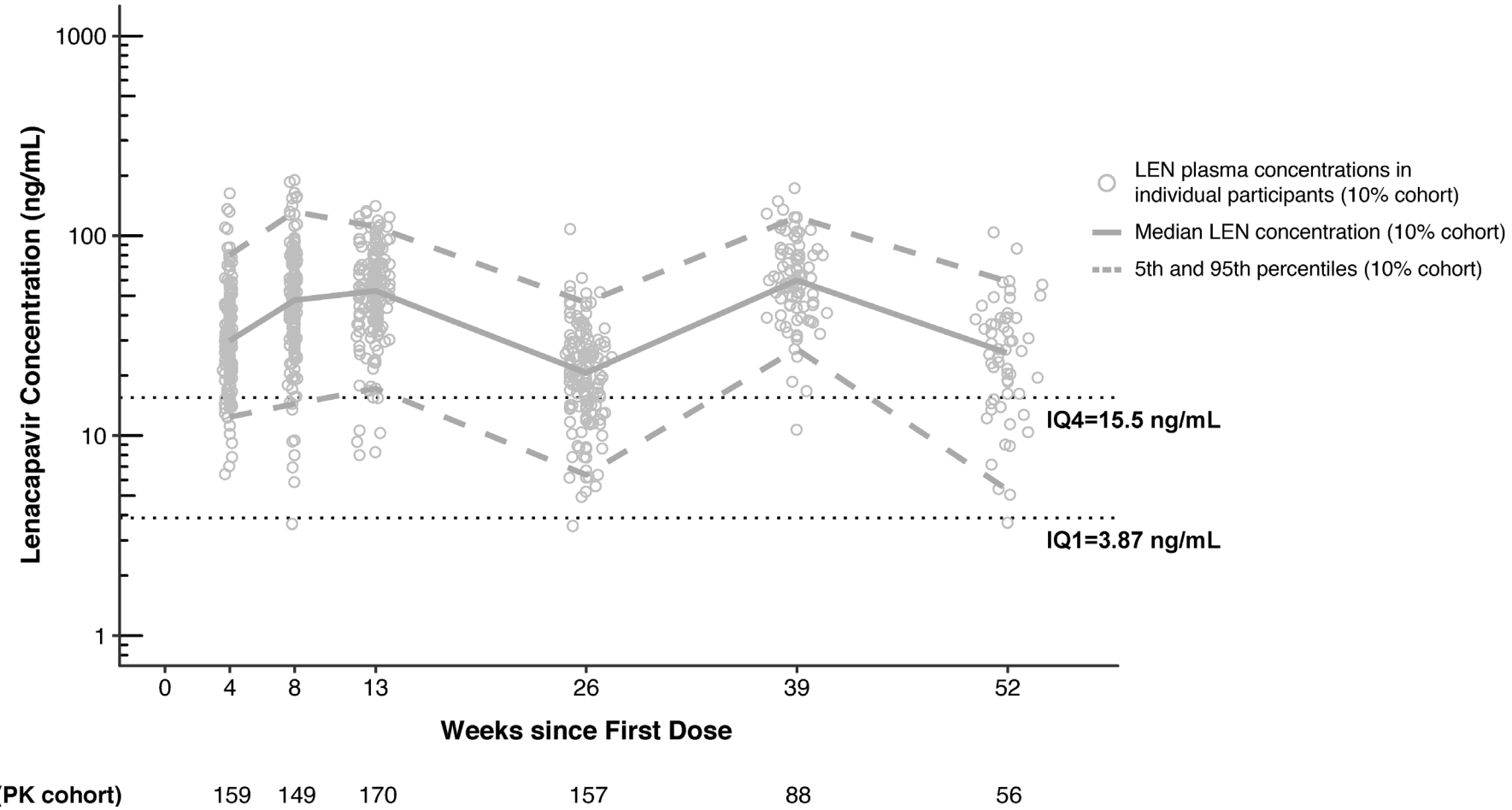
Adherence by TFV-DP Concentration in 10% Cohort



[a]Participants randomized and treated after the clinical hold was lifted. [b]Preselected 10% sample of participants assessed for TFV-DP concentrations in DBS (F/TDF: low < 350, medium ≥ 350 to < 700, high ≥ 700 fmol/punch). DBS reflects adherence over the past 8–12 weeks.[1]

1. Castillo-Mancilla JR, et al. *AIDS Res Hum Retroviruses*. 2013;29:384-90.

LEN Plasma Concentrations in the 10% PK Cohort



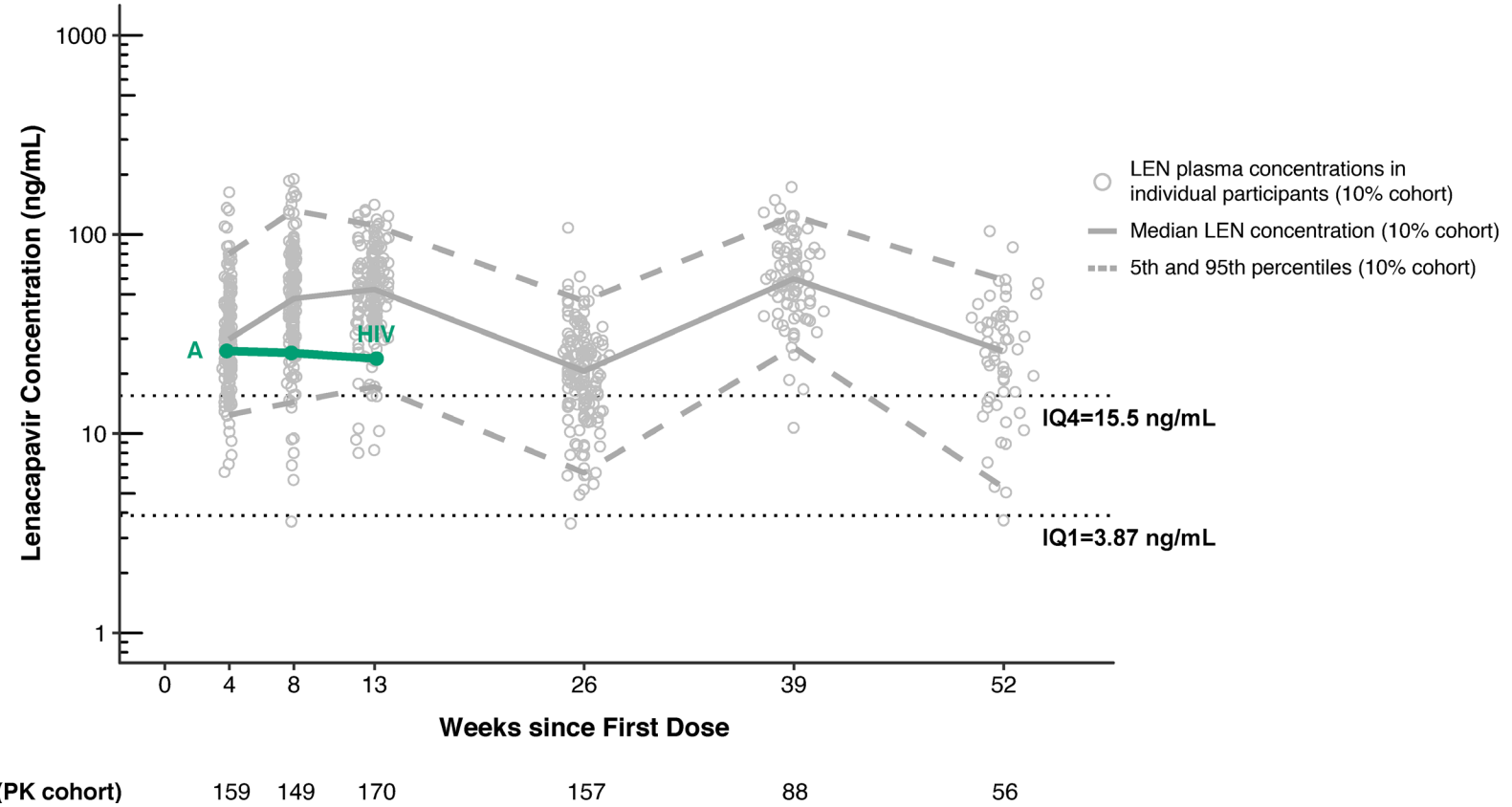
The PK cohort was a randomly preselected, representative sample of 10% of participants. IQ was defined as the protein-adjusted 95% effective concentration in MT-4 cells, and IQ4 as four times the protein-adjusted 95% effective concentration, in vitro.[1] **IQ**, inhibitory quotient. 1. Margot N, et al. Poster O-324 presented at: HIV Glasgow; 2020.

LEN Plasma Concentrations in Participant A

Participant A:
- Transgender woman with latent syphilis diagnosed and treated at baseline
- Engaged in transactional sex
- Diagnosed with HIV at Week 13 with standard HIV testing

HIV diagnosis

	BL	W4	W8	W13
Rapid Ag/Ab	(-)	(-)	(-)	(+)
Central Ag/Ab	(-)	(-)	(-)	(+)
HIV-1/2 Ab diff				(HIV-1+/ HIV-2-)
Qualitative RNA				(+)
Quantitative RNA, c/mL	ND	ND[a]	ND[a]	934,000



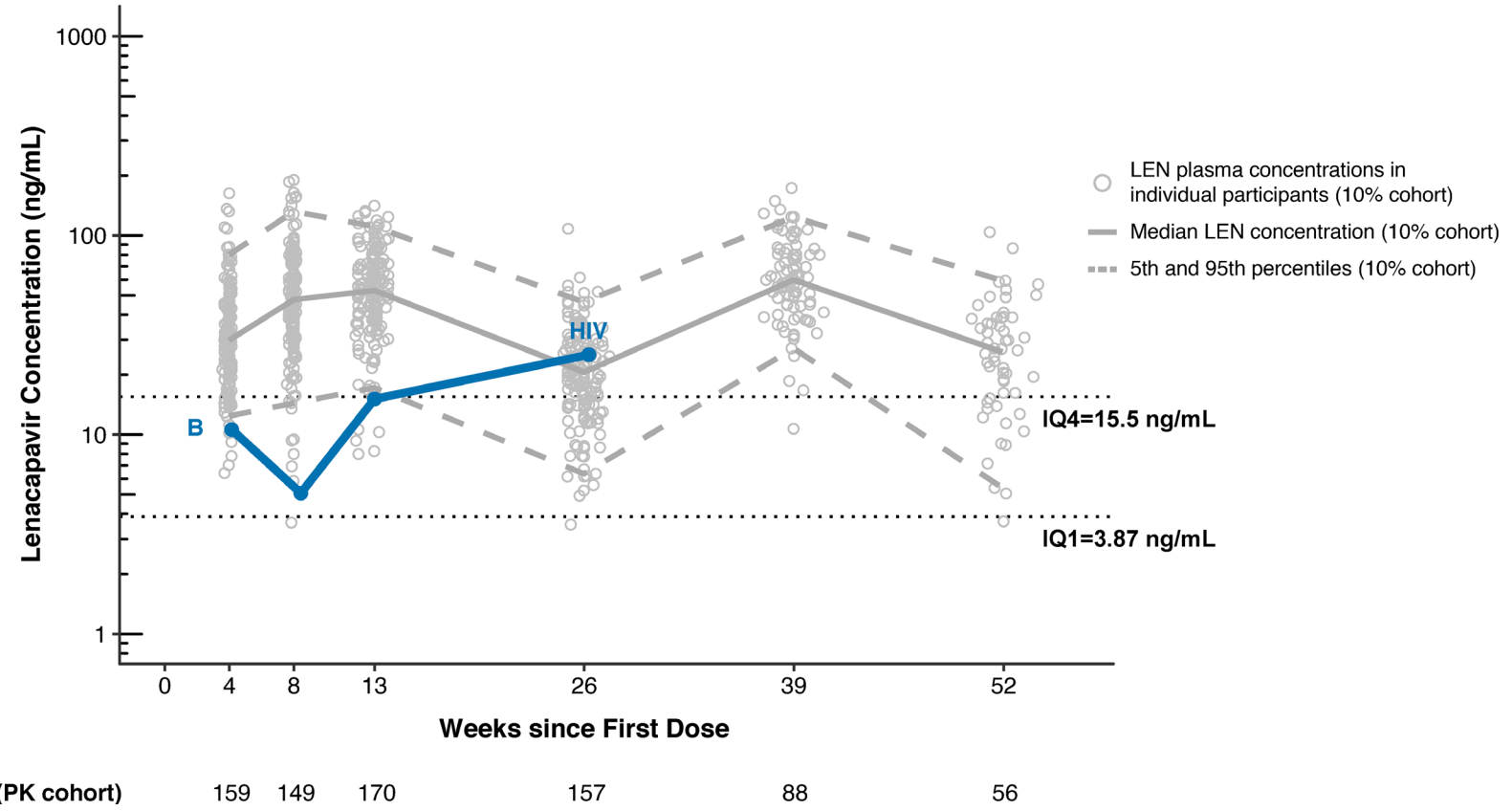
IQ was defined as the protein-adjusted 95% effective concentration in MT-4 cells, and IQ4 as four times the protein-adjusted 95% effective concentration, in vitro.[1] LEN plasma concentrations for Participant A at Weeks 4, 8, and 13 were 26 ng/mL (IQ6.7), 25.4 ng/mL (IQ6.6), and 23.8 ng/mL (IQ6.2). Participant A was diagnosed at Week 13 with positive rapid and central laboratory fourth-generation Ag/Ab tests, Ab differentiation test positive for HIV-1 and negative for HIV-2, a positive qualitative RNA test, and VL of 934,000 copies/mL; retrospective VL testing from Week 8 was negative by standard HIV testing (LLOQ, 20 copies/mL) and 4.8 copies/mL by HIV-1 RNA single-copy testing. [a]Quantitative RNA tests run from archived samples after HIV diagnosis. **c**, copies; **diff**, differentiation; **LLOQ**, lower limit of quantification; **ND**, no HIV-1 RNA detected; **VL**, viral load. 1. Margot N, et al. Poster O-324 presented at: HIV Glasgow; 2020.

LEN Plasma Concentrations in Participant B

Participant B:
- Cisgender gay man with rectal chlamydia diagnosed and treated at screening
- Diagnosed with HIV at Week 26 with standard HIV testing

HIV diagnosis

	BL	W4	W8	W13	W26
Rapid Ag/Ab	(-)	(-)	(-)	(-)	(-)
Central Ag/Ab	(-)	(-)	(-)	(-)	(+)
HIV-1/2 Ab diff					(HIV-1+/ HIV-2-)
Qualitative RNA					(+)
Quantitative RNA, c/mL	ND			ND[a]	14,100



Participants A and B were diagnosed with standard serologic HIV testing at Weeks 13 and 26, respectively; both participants had no evidence of delayed HIV diagnosis by RNA, and had LEN concentrations within the range of the 10% random subset of participants and similar to prior studies.[1] Both participants had N74D capsid mutation at HIV diagnosis

IQ was defined as the protein-adjusted 95% effective concentration in MT-4 cells, and IQ4 as four times the protein-adjusted 95% effective concentration, in vitro.[2] LEN plasma concentrations for Participant B at Weeks 4, 8, 13, and 26 were 10.6 ng/mL (IQ2.7), 5.1 ng/mL (IQ1.3), 15.1 ng/mL (IQ3.9), and 25.2 ng/mL (IQ6.5). Participant B was diagnosed at Week 26 with a negative rapid fourth-generation Ag/Ab test, positive central laboratory fourth-generation Ag/Ab test, Ab differentiation test positive for HIV-1 and negative for HIV-2, positive qualitative RNA test, and VL of 14,100 copies/mL; retrospective standard VL testing from Week 13 was negative (LLOQ, 20 copies/mL) as well as by HIV-1 RNA SCA.

[a]Quantitative RNA tests run from archived samples after HIV diagnosis. 1. Jogiraju V, et al. *Clin Pharmacol Ther* 2023;113;S1. 2. Margot N, et al. Poster O-324 presented at: HIV Glasgow; 2020.

LEN and F/TDF Are Safe and Well Tolerated

AE,[a] n (%)	LEN, n = 2183	F/TDF, n = 1088
Any	1607 (74)	803 (74)
Grade ≥ 2	1173 (54)	594 (55)
Grade ≥ 3	91 (4)	65 (6)
Serious AEs	71 (3)	43 (4)
AEs leading to discontinuation of study drug	7 (< 1)	7 (< 1)[b]
AEs occurring in ≥ 5% of participants		
Rectal chlamydia infection	289 (13)	128 (12)
Oropharyngeal gonococcal infection	283 (13)	119 (11)
Rectal gonococcal infection	233 (11)	99 (9)
Upper respiratory tract infection	148 (7)	77 (7)
Diarrhea	146 (7)	75 (7)
Headache	119 (5)	76 (7)
Influenza	120 (5)	66 (6)
Latent syphilis	114 (5)	44 (4)
Nausea	89 (4)	67 (6)
Laboratory abnormalities with ≥ 1 post-baseline result[c]		
Any grade ≥ 1	1822 (85)	937 (87)

There were four deaths in the LEN group and two deaths in the F/TDF group[d]; none were related to study drugs per the investigator.

Median change from baseline in eGFR:

- Week 26: +1.2 mL/min in the LEN group vs -3.0 mL/min in the F/TDF group ($P < 0.0001$)
- Week 52: +0.6 mL/min in the LEN group vs -2.9 mL/min in the F/TDF group ($P = 0.0024$)

The frequency of AEs and laboratory abnormalities was similar between arms, with the exception of changes in eGFR (significantly different at Week 26 and Week 52). Safety was consistent with prior LEN and F/TDF trials[1-5]

[a]Excluding ISRs; AEs coded according to Medical Dictionary for Regulatory Activities, Version 27.0, and graded by the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, Version 2.1.
[b]AEs leading to discontinuation of study drug in more than one participant in any group: decreased creatinine renal clearance (two participants in the F/TDF group; 0.2%). [c]Among participants with post-baseline results: LEN, n = 2153; F/TDF, n = 1071.
[d]LEN group: cerebrovascular accident and pulmonary thromboembolism, car collision, sudden death with an undetermined cause, and suicide; F/TDF group: intracranial hemorrhage and undetermined cause. **ISR**, injection-site reaction.

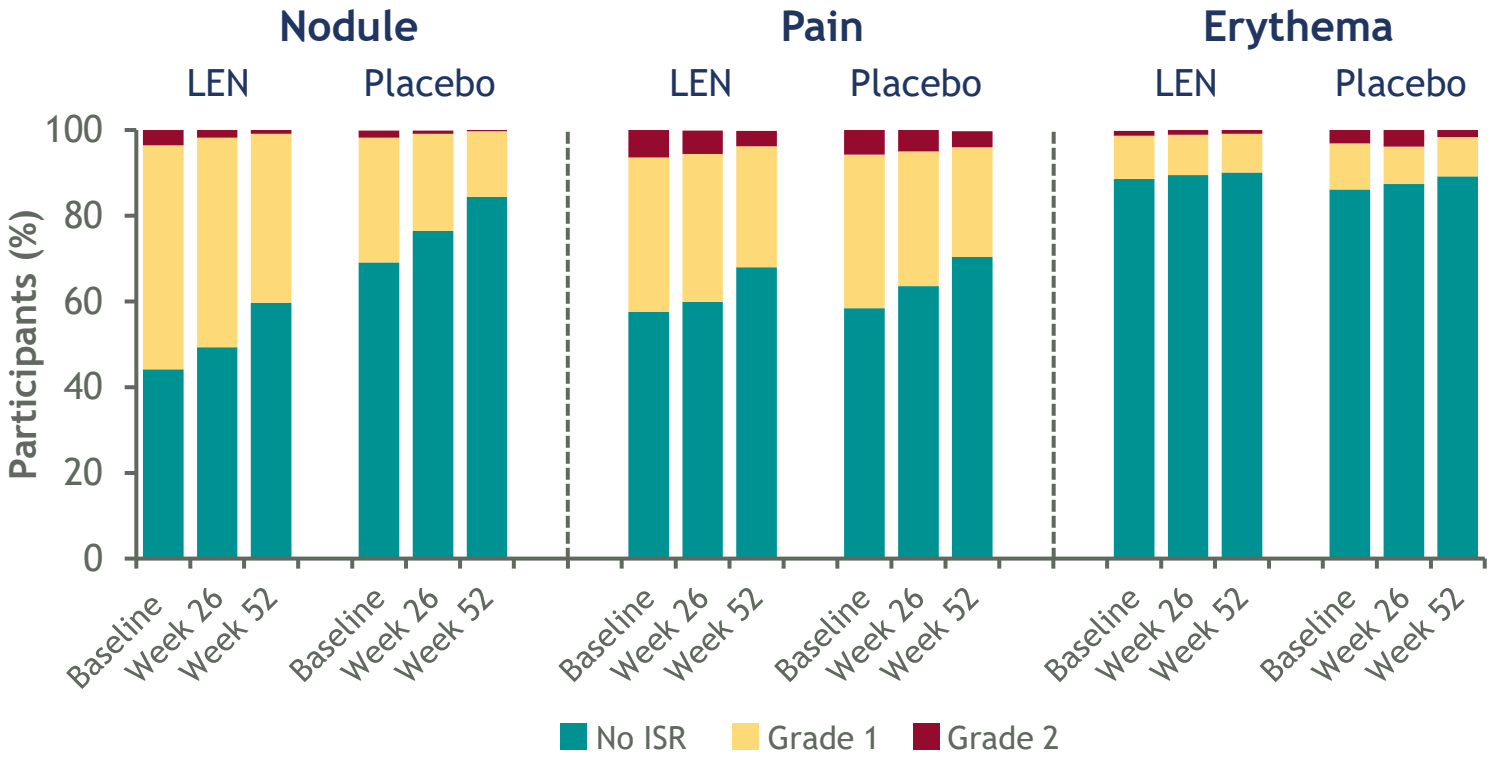
1. Gupta SK, et al. *Lancet HIV*. 2023;10:e15-23. 2. Ogbuagu O, et al. *Lancet HIV*. 2023;10:e497-505. 3. Mayer KH, et al. *Lancet*. 2020;396:239-54. 4. Baeten JM, et al. *N Engl J Med*. 2012;367:399-410. 5. Bekker L-G, et al. *N Engl J Med*. 2024;391:1179-92.

ISR Frequency and Grade Numerically Diminish With Subsequent Injections

LEN is injected into the SC space and forms a drug depot that may be palpable under the skin but is usually not visible

As the drug elutes over time, the depot gets smaller, and the nodules resolve or reduce in size substantially prior to the next injection

- Median (Q1, Q3) duration of nodules:
  - Nodules: LEN 183 (89, 274) vs placebo 64 (19, 98) days
- Pain and erythema:
  - Similar with LEN and placebo injections, suggesting they were due to an injection, rather than the drug product



Among 10,094 LEN or 5145 placebo injections, only 26 in LEN group and 3 in the F/TDF group discontinued due to AEs of ISRs; frequency of ISRs, including nodules, decreased with subsequent doses (also observed previously in PURPOSE 1[1] and HIV treatment trials[2])

AEs coded according to Medical Dictionary for Regulatory Activities, Version 27.0. Subcutaneous nodules, injection-site pain, and erythema were the most commonly reported ISRs; over the period of study, they occurred in 63.4%, 56.4 %, and 17.3% of participants in the LEN group, respectively, vs 39.2%, 53.4%, and 19.4% of participants given placebo injections; Grade 1 and 2 ISRs are shown; Grade 3 ISRs in the LEN group: n = 4 pain, n = 3 erythema; F/TDF group: n = 1 pain. There were no Grade 3 AEs of injection-site nodule in either group. Grade 3 injection-site ulcers occurred in seven (0.3%) participants in the lenacapavir group and zero participants in the F/TDF group. Pain mitigation measures including ice or cold compress administration before and after the injection were implemented during the trial. Inappropriate injection technique, especially injection into the dermis rather than the SC space, was associated with more severe ISRs. LEN n: baseline, 2183; Week 26, 1859; Week 52, 744. Placebo n: baseline, 1088; Week 26, 946; Week 52, 379.
Q, quartile. 1. Bekker L-G, et al. *N Engl J Med*. 2024;391:1179-92. 2. Kumar P, et al. Abstract EPB184 presented at: 24th International AIDS Conference; July 29-August 2, 2022; Montreal, Canada.

PURPOSE 2 Conclusions

- Twice-yearly LEN was highly efficacious for HIV prevention among the most globally, racially, ethnically diverse population of 17- to 74-year-old cisgender gay, bisexual, and other men; transgender women; transgender men; and gender nonbinary people
  - LEN reduced HIV incidence by 96% vs background HIV incidence and 89% vs daily oral F/TDF
- There is no evidence that LEN delayed HIV seroconversion or diagnosis by standard HIV serologic testing
- F/TDF adherence was high but declined over time
- Over 99.9% of participants on LEN did not acquire HIV, despite high levels of sexual exposure, chemsex, and STIs
- LEN and F/TDF were safe and well tolerated; ISRs were consistent with mechanism of action and administration of SC LEN. Discontinuations due to AEs of ISRs were uncommon

Twice-yearly LEN offers an efficacious, safe, and well-tolerated new choice for HIV prevention that does not depend on daily oral adherence and has the potential to increase PrEP uptake and persistence and thus potentially reduce the global burden of HIV

PURPOSE 2 Next Steps

Global regulatory filings are urgently in progress so that LEN, if approved, can be authorized for all those who need or want PrEP, particularly those most disproportionately affected by HIV

Participants are being offered LEN and will receive LEN through the study until it is available in their location

Gilead has been developing a strategy to enable broad, sustainable access globally

- Royalty-free, voluntary licensing agreements are in place with six pharmaceutical manufacturers to make generic LEN available in 120 high-incidence, resource-limited countries, covering LEN for HIV prevention, if approved, and treatment in HTE adults with MDR HIV
- These agreements are just one component of Gilead's overall global strategy to enable broad, sustainable access to LEN for PrEP, if approved, prioritizing timely regulatory filings, engagement with partners and governments, and manufacturing planning, including for Argentina, Brazil, Mexico, Peru, and the US

Please see the full access statements at Gilead.com[a,b]

PURPOSE 1 NCT identifier: NCT04994509; PURPOSE 2: NCT04925752; PURPOSE 3: NCT06101329; PURPOSE 4: NCT06101342. PURPOSE studies available at: https://www.purposestudies.com (accessed October 4, 2024). [a]https://www.gilead.com/company/company-statements/2024/updated-statement-on-access-planning-in-high-incidence-resource-limited-countries-for-lenacapavir-for-hiv-prevention (accessed October 4, 2024). [b]https://www.gilead.com/news/news-details/2024/gilead-signs-royalty-free-voluntary-licensing-agreements-with-six-generic-manufacturers-to-increase-access-to-lenacapavir-for-hiv-prevention-in-high-incidence-resource-limited-countries (accessed October 4, 2024). **FR**, France; **HTE**, heavily treatment-experienced; **MDR**, multidrug-resistant; **PWID**, people who inject drugs; **NCT**, National Clinical Trial; **UK**, United Kingdom.

PURPOSE 2 Acknowledgments

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PURPOSE 2 Study Team

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