PURPOSE
Prevention with PURPOSE

IDWeek

Update on Lenacapavir for PrEP: Results From the Interim Analyses of PURPOSE 1 and PURPOSE 2

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Disclosures

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- Chair of Category H (HIV) for the 2024 IDWeek Program Committee
- Vice Chair for the HIV Medicine Association
- 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 2 Study Team all vouch for the data and analysis
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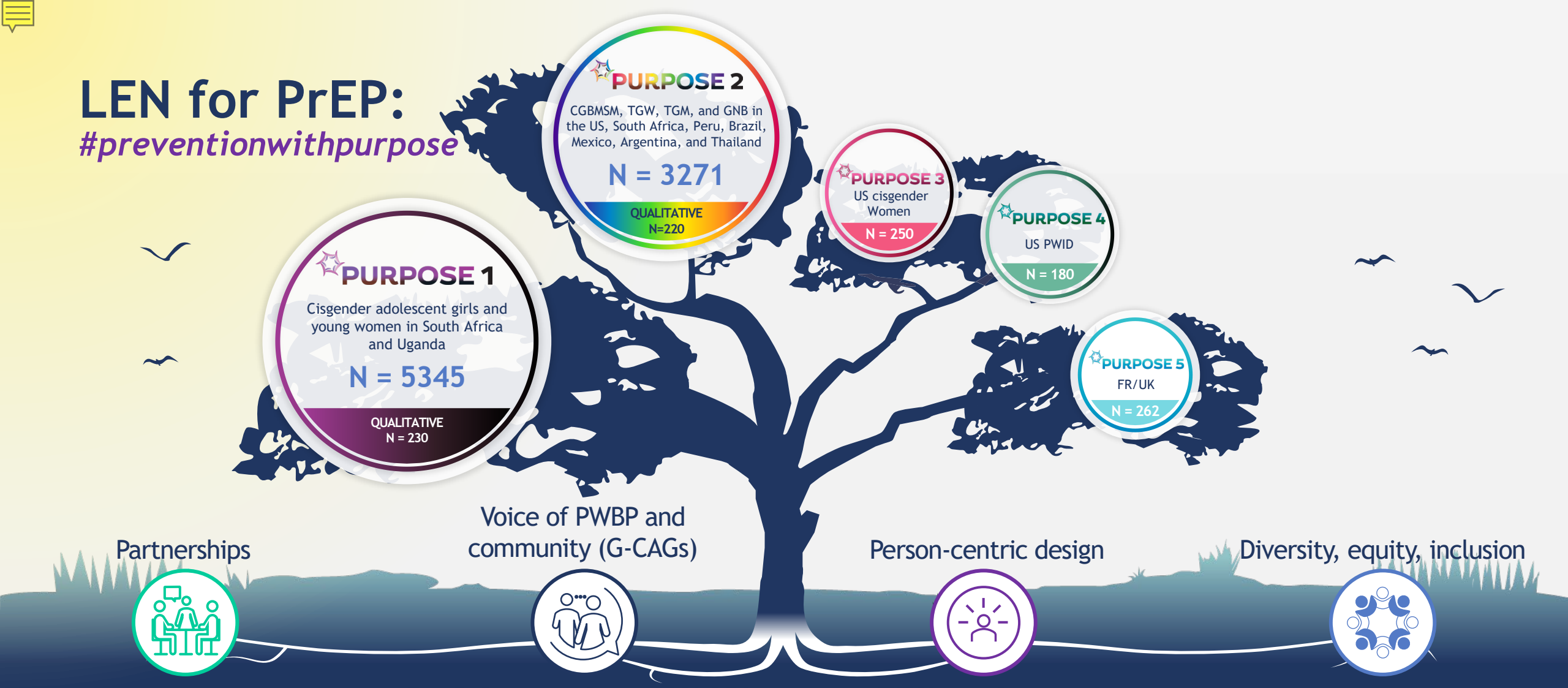
CME, continuing medical education; **G-CAG**, Global Community Advisory Group; **PI**, principal investigator.

LEN for PrEP:

#preventionwithpurpose



Proof of concept that capsid inhibitors prevent SHIV in non-human primates;
Robust pharmacokinetic and safety database in persons with and without HIV;

Capella **LEN for HIV Tx in MDR HIV**

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).
Access statements: 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); 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).
CGBMSM, cisgender gay and bisexual men who have sex with men; **FR**, France; **GNB**, gender nonbinary individuals; **LEN**, lenacapavir; **MDR**, multi-drug resistant; **NCT**, National Clinical Trial; **PrEP**, pre-exposure prophylaxis; **PWBP**, people who would benefit from PrEP; **PWID**, people who inject drugs; **SHIV**, simian-human immunodeficiency virus; **TGM**, transgender men; **TGW**, transgender women; **Tx**, treatment; **UK**, United Kingdom; **US**, United States.

Cisgender Women and Populations Disproportionately Affected by HIV Incidence Need New HIV Prevention Choices

The uptake of, adherence to, and persistence on oral PrEP remains suboptimal in populations globally, with 1.3 million new HIV infections annually[1-11]

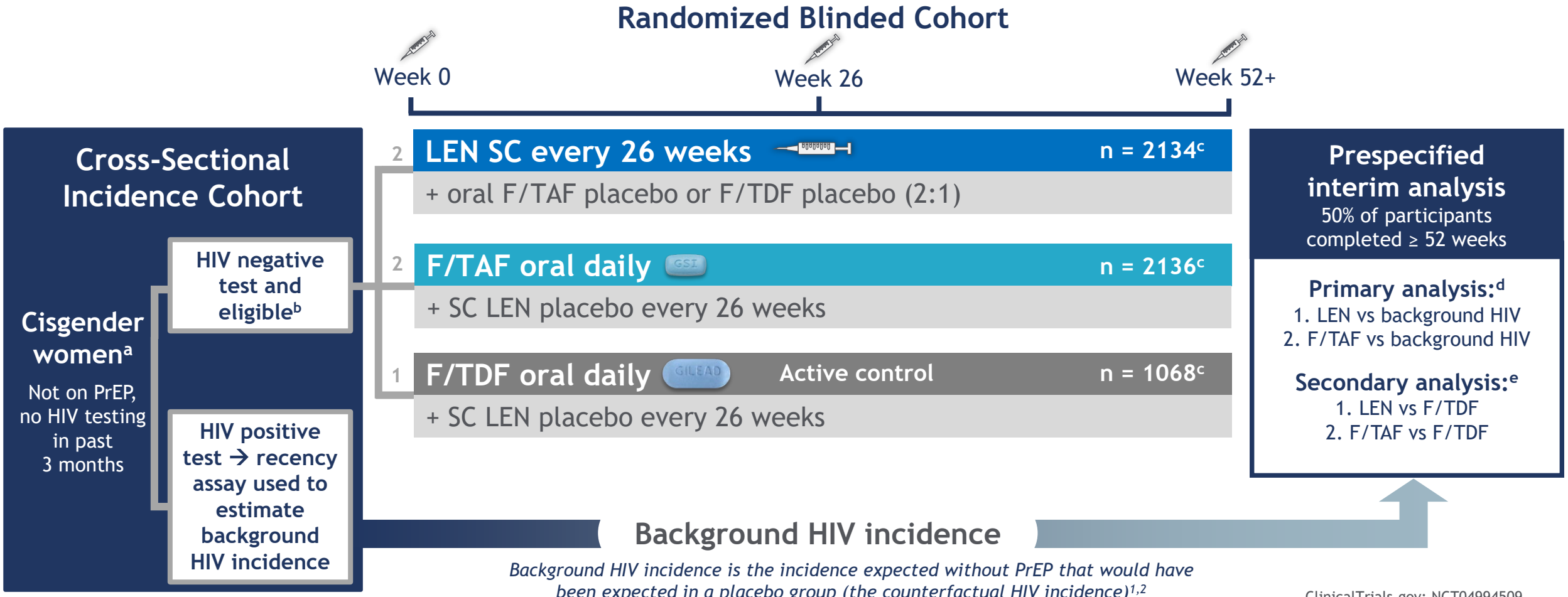
We need to develop new PrEP options that do not require daily oral adherence to pills or frequent clinic visits

LEN is a first-in-class, multistage HIV-1 capsid inhibitor with high potency and a long half-life, supporting twice-yearly SC injection[12,13]

We evaluated the safety and efficacy of twice-yearly SC LEN for HIV prevention in cisgender women (PURPOSE 1) and 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 (PURPOSE 2)

SC, subcutaneous. **1.** de Dieu Tapsoba J, et al. *AIDS Care*. 2021;33(6):712-20. **2.** Mugwanya KK, et al. Abstract 993 presented at: Conference on Retroviruses and Opportunistic Infections; March 4-7, 2019; Seattle, WA. **3.** Velloza J, et al. *AIDS Behav*. 2023;27(1):279-89. **4.** Chakare T, et al. Abstract OAD0604 presented at: 23rd International AIDS Conference; July 6-10, 2020; Brisbane, Australia. **5.** Klein H, Washington TA. *J Gay Lesbian Soc Serv*. 2020;32:99-114. **6.** Baral SD, et al. *Lancet Infect Dis*. 2013;13:214-22. **7.** Kanny D, et al. *MMWR Morb Mortal Wkly Rep*. 2019;68:801-6. **8.** Poteat T, et al. *J Acquir Immune Defic Syndr*. 2016;72(suppl. 3):S210-9. **9.** Sullivan PS, et al. *J Int AIDS Soc*. 2020;23:e25461. **10.** Torres TS, et al. *Lancet Reg Health Am*. 2023;28:100642. **11.** Joint United Nations Programme on HIV/AIDS. https://aidsinfo.unaids.org (accessed October 10, 2024). **12.** Segal-Maurer S, et al. *N Engl J Med*. 2022;386:1793-803. **13.** Link JO, et al. *Nature*. 2020;584:614-18.

PURPOSE 1 Study Design



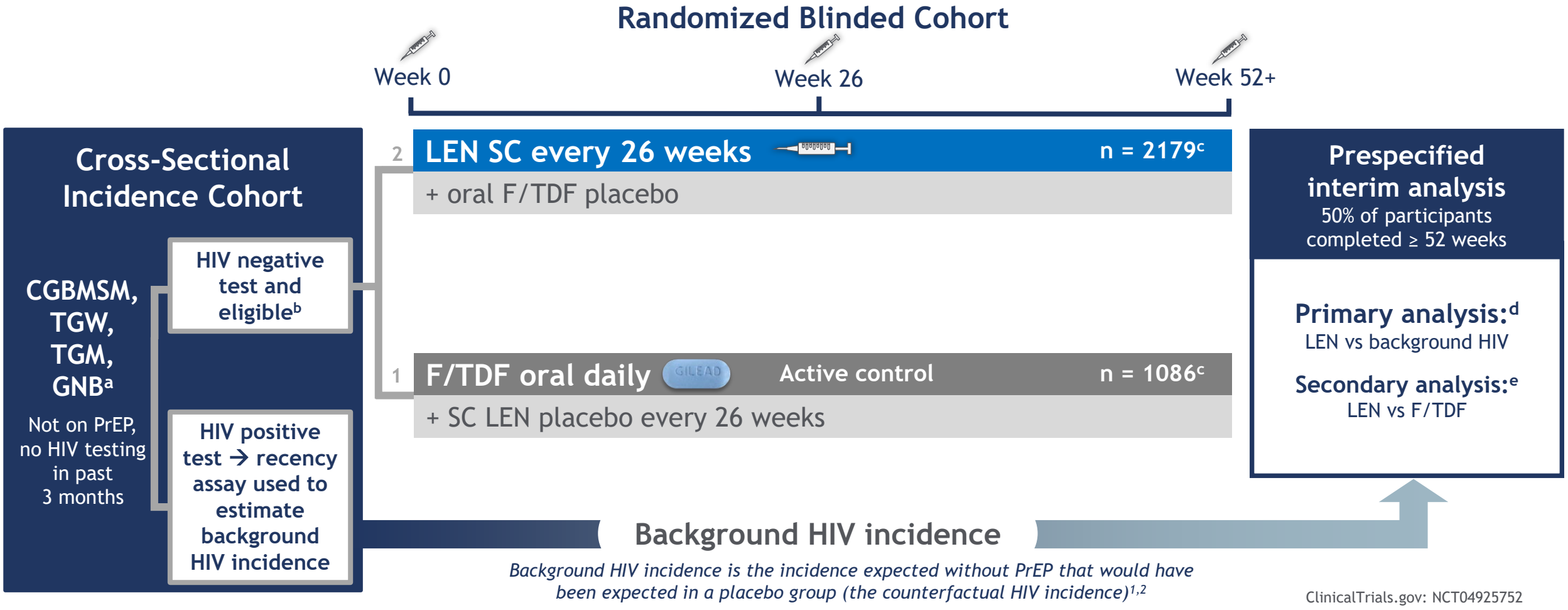
Background HIV incidence is the incidence expected without PrEP that would have been expected in a placebo group (the counterfactual HIV incidence)[1,2]

ClinicalTrials.gov: NCT04994509

[a]The first participant was screened in August 2021, the 50th percentile participant was randomized in May 2023, and the last participant was randomized in September 2023. [b]Eligibility criteria included: 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 or likelihood ratio test if there were zero infections.[1,2] [e]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.

1. Gao F, et al. *Stat Commun Infect Dis.* 2021;13(1):20200009. **2.** Shao Y, Gao F. *Stat Commun Infect Dis.* 2024;16(1):20230004.

PURPOSE 2 Study Design



On Days 1 and 2, all participants received a pharmacologic 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.

1. Gao F, et al. *Stat Commun Infect Dis.* 2021;13(1):20200009. **2.** Shao Y, Gao F. *Stat Commun Infect Dis.* 2024;16(1):20230004.

Baseline Characteristics

PURPOSE 1

Characteristic	LEN, n = 2138	F/TAF, n = 2137	F/TDF, n = 1070
Age, years, median (range)	21 (16-25)	21 (16-26)[a]	21 (16-25)
Age 16 to <18, years, n (%)	56 (2.6)	45 (2.1)	23 (2.1)
Black race,[b] n (%)	2135 (99.9)	2136 (100)	1068 (99.8)
Highest education level college/university,[c] n (%)	183 (8.6)	198 (9.3)	109 (10.2)
Marital status, n (%)			
Married	26 (1.2)	30 (1.4)	17 (1.6)
Living with primary partner	148 (6.9)	132 (6.2)	73 (6.8)
STIs, n (%)			
Chlamydia trachomatis	520 (24.3)	562 (26.3)	263 (24.6)
Neisseria gonorrhoeae	197 (9.2)	178 (8.3)	90 (8.4)
Trichomonas vaginalis	154 (7.2)	165 (7.7)	82 (7.7)
Syphilis	57 (2.7)	63 (2.9)	29 (2.7)
Any prior use of PrEP, n (%)	143 (6.7)	121 (5.7)	71 (6.6)
Any prior HIV testing, n (%)	1713 (80.1)	1731 (81.0)	860 (80.4)
Median time since last HIV test, months (Q1, Q3)	6.8 (4.7, 11.5)	6.6 (4.8, 11.0)	6.5 (4.6, 11.0)

PURPOSE 2

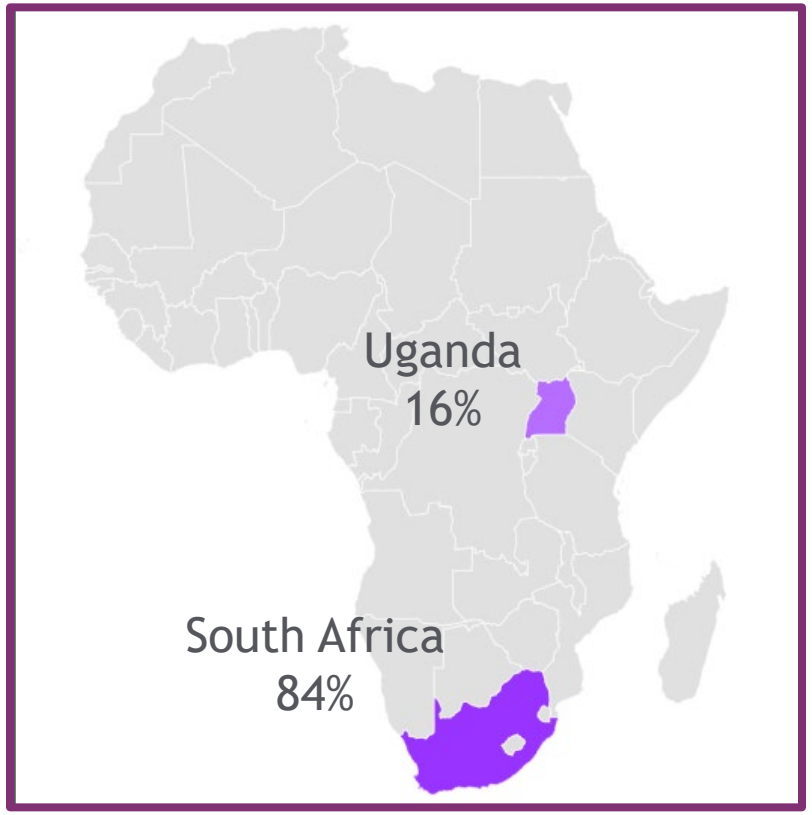
Characteristic	LEN, n = 2183	F/TDF, n = 1088
Age, years, median (range)	28 (17-74)	29 (17-73)
Age 16 to ≤ 25, years, n (%)	752 (34.4)	344 (31.6)
Non-White race,[d] n (%)	1453 (66.8)	742 (68.3)
Hispanic/Latine ethnicity,[e] n (%)	1378 (63.2)	675 (62.0)
Gender identity, n (%)		
Cisgender man	1697 (77.7)	846 (77.8)
Gender-diverse	486 (22.3)	242 (22.2)
STIs, n (%)		
Chlamydia trachomatis, Neisseria gonorrhoeae or Trichomonas vaginalis[f,g]	382 (18.2)	207 (20.0)
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)

Baseline demographics and clinical characteristics were balanced across randomized groups

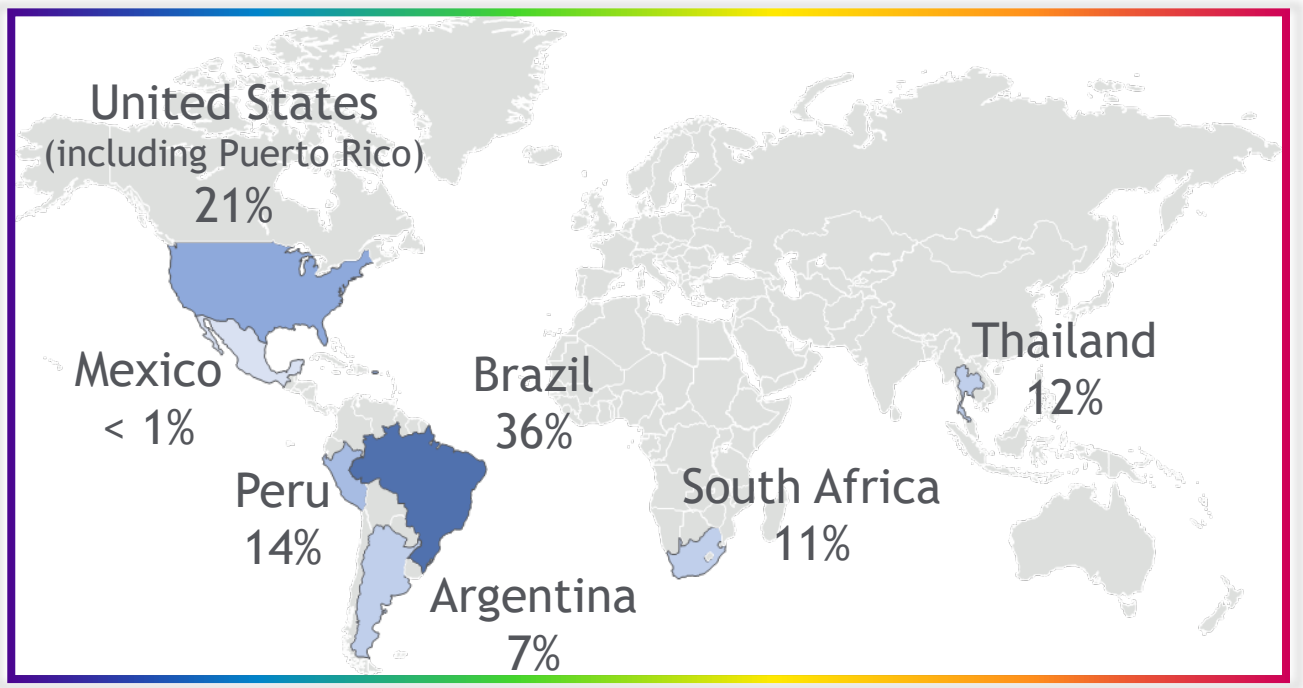
PURPOSE 1: 7 participants were subsequently determined to have had HIV infection at the time of randomization, and thus 5338 were included in the modified ITT efficacy analysis. PURPOSE 2: 6 participants were subsequently determined to have had HIV infection at the time of randomization, and thus 3265 were included in the modified ITT efficacy analysis. [a]1 participant was aged 25 years at screening but turned 26 by randomization—this was not a violation of eligibility criteria. [b]All non-Black participants were multiracial. [c]Sample size LEN: 2136; F/TAF: 2134; F/TDF: 1069. [d]Data were unavailable for 8 participants in the LEN group and 2 in the F/TDF group. [e]Data were unavailable for 1 participant in the LEN group. [f]LEN: n = 2096; F/TDF: n = 1036. ITT participants with any STI laboratory test while at risk of HIV in study. Testing for T vaginalis was performed at investigator discretion (n = 1 T vaginalis diagnosed at baseline in the LEN group). [g]Diagnoses for chlamydia or gonorrhea were based on rectal, pharyngeal, and urine testing at a central laboratory. **ITT**, intention-to-treat; **Q**, quartile; **STI**, sexually transmitted infection.

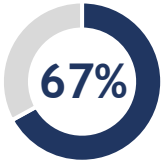
Global Distribution of Participants

PURPOSE 1

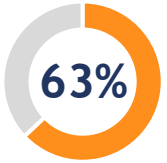


PURPOSE 2

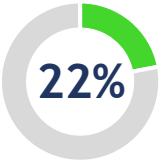




Non-White



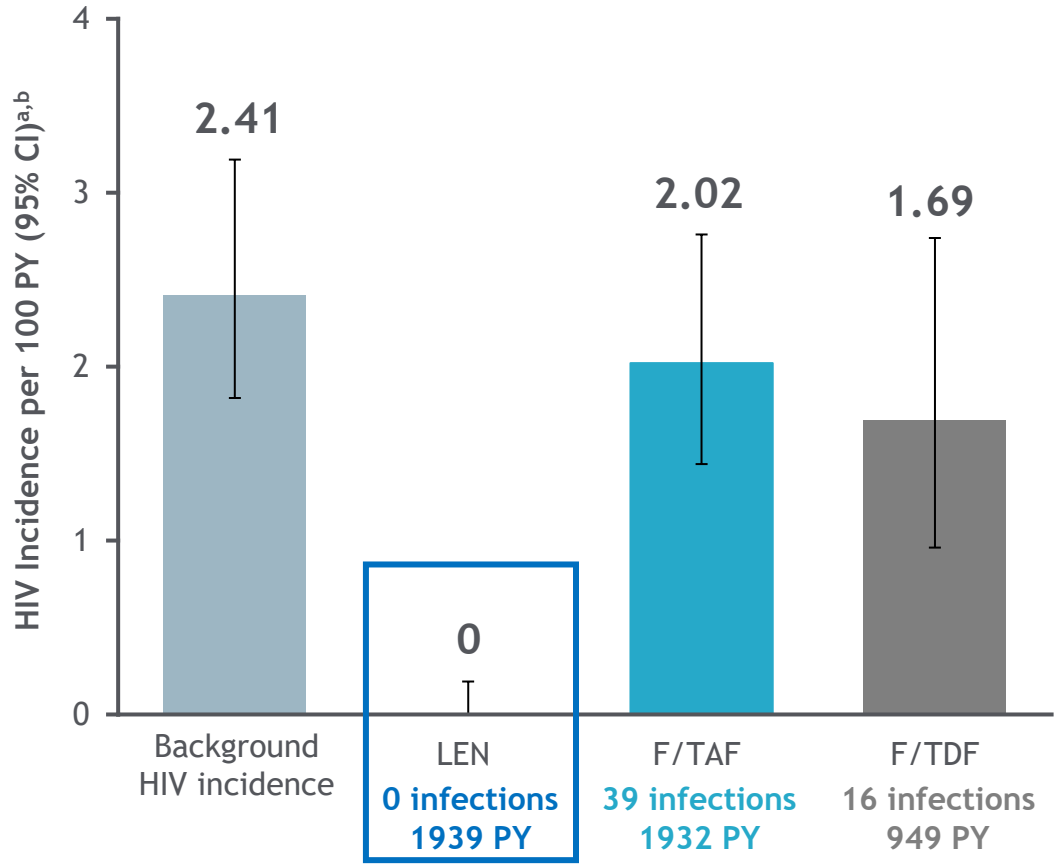
Hispanic/
Latine



Gender-diverse

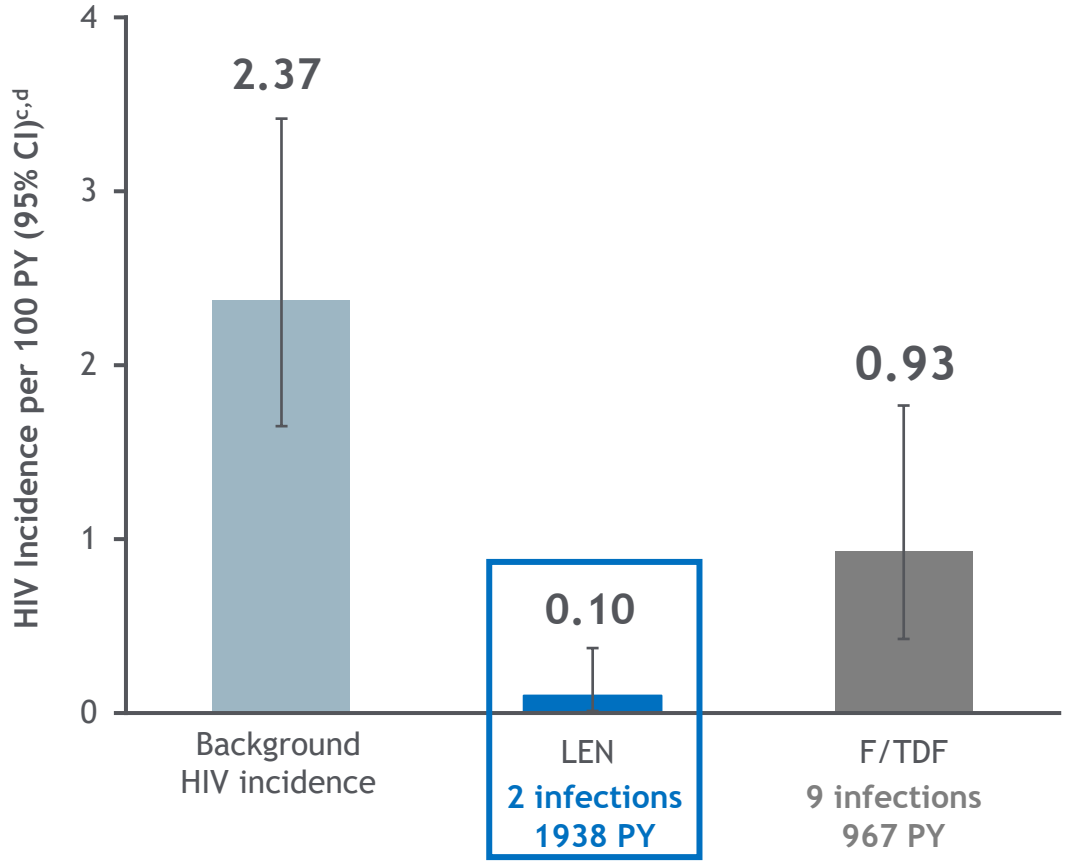
Darker shading corresponds to a higher proportion of participants.

PURPOSE 1: Zero HIV Infections in Cisgender Women Receiving LEN



Median follow-up duration: 44.0 weeks

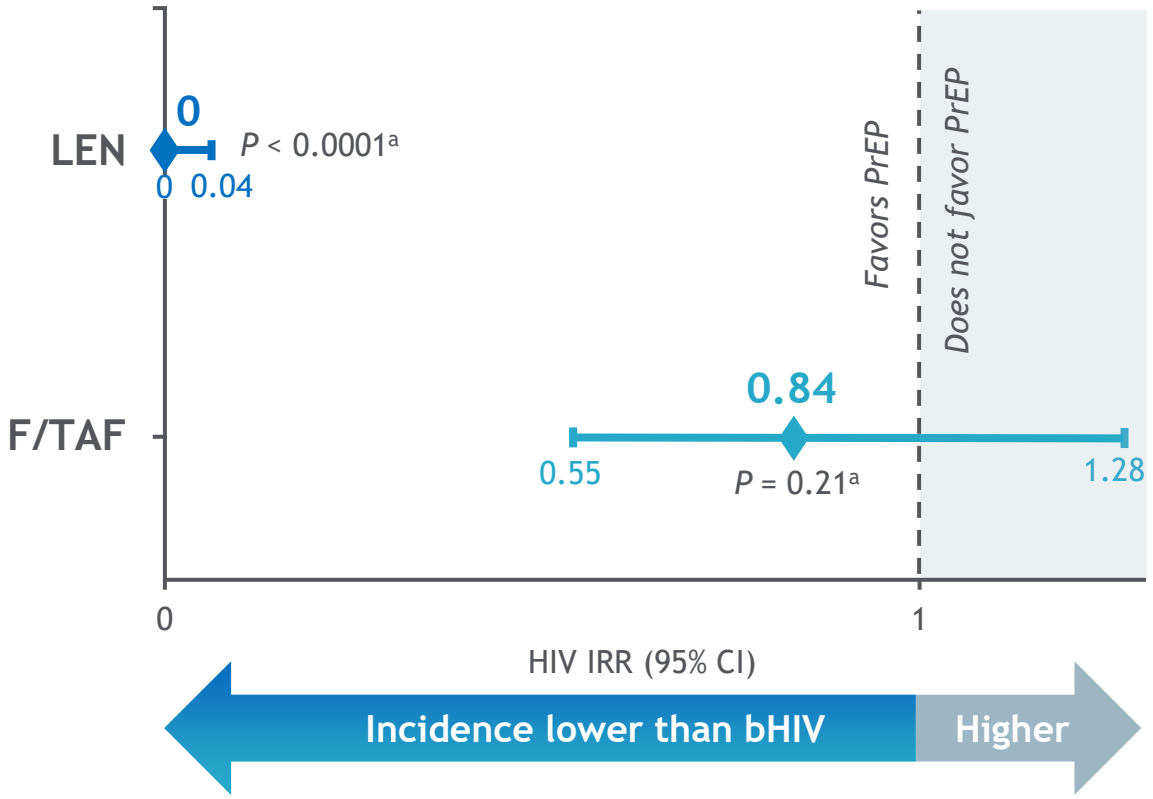
PURPOSE 2: Two HIV Infections in Participants Receiving LEN



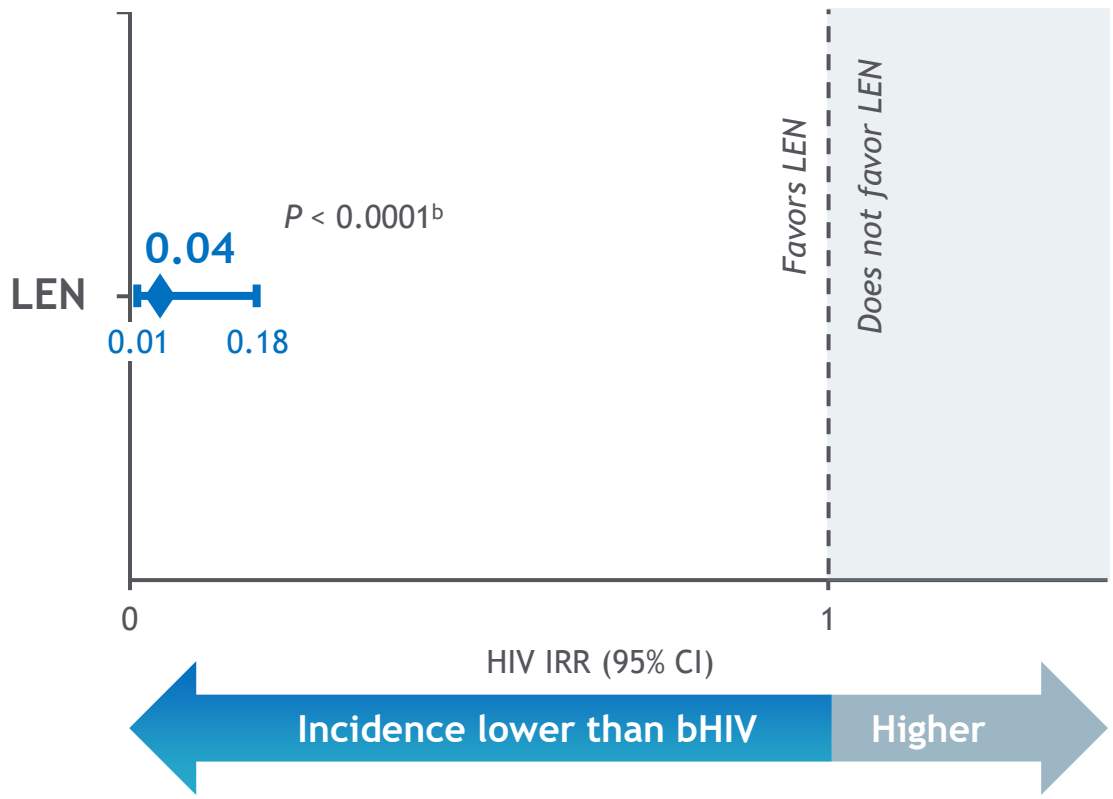
Median follow-up duration: 39.4 weeks

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

PURPOSE 1 Primary Analysis: LEN Has 100% Efficacy for PrEP



PURPOSE 2 Primary Analysis: LEN Has 96% Efficacy for PrEP

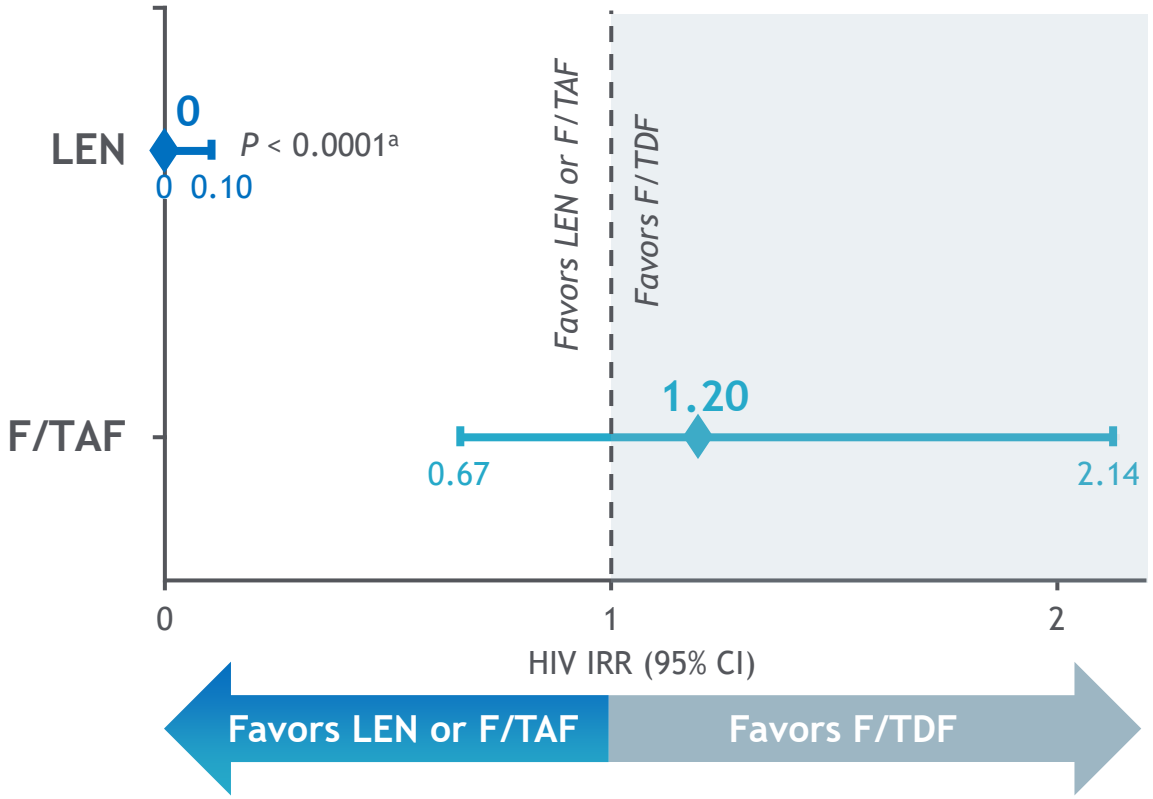


LEN reduced HIV infections by 100% in PURPOSE 1 and by 96% in PURPOSE 2 compared with background HIV incidence; in PURPOSE 1, F/TAF was not different from background HIV incidence

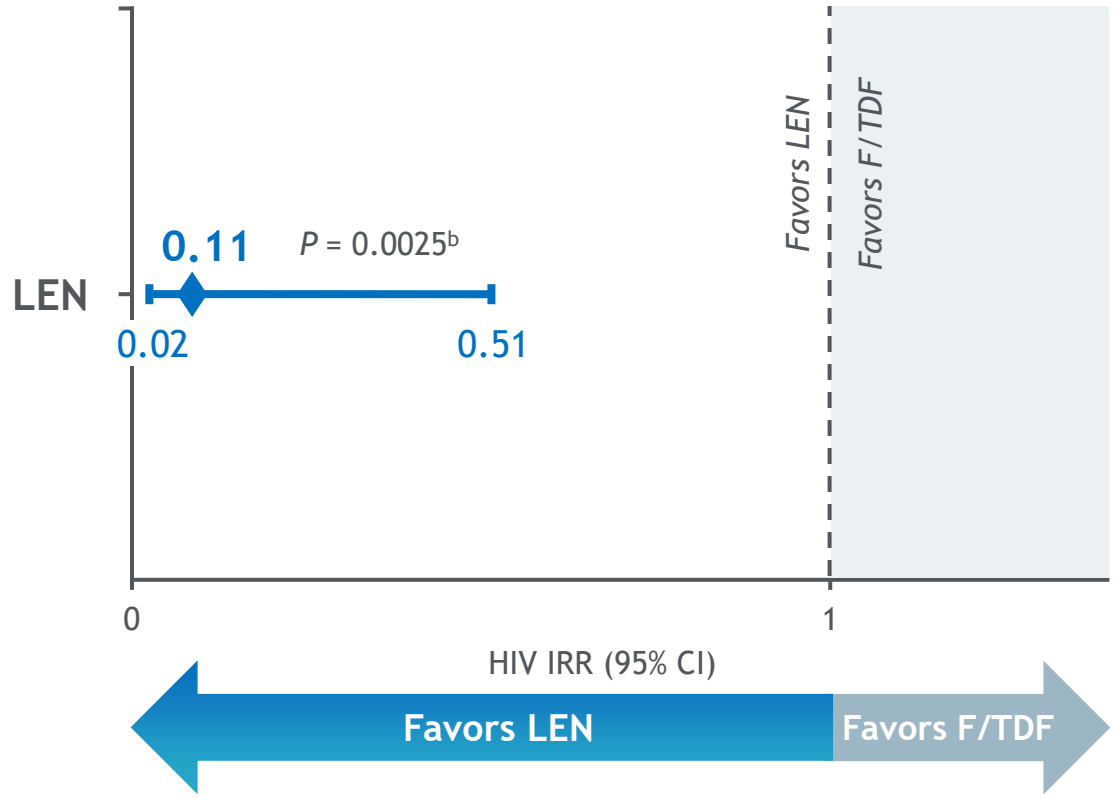
[a]HIV IRR vs background HIV was assessed using a likelihood ratio test (LEN, due to zero infections), and a Wald test (F/TAF).[1,2] [b]HIV IRR vs background HIV was assessed using a Wald test.[2]
bHIV, background HIV incidence.

1. Shao Y, Gao F. *Stat Commun Infect Dis.* 2024;16(1):20230004. **2.** Gao F, et al. *Stat Commun Infect Dis.* 2021;13(1):20200009.

PURPOSE 1 Secondary Analysis: LEN Superior to F/TDF



PURPOSE 2 Secondary Analysis: LEN Superior to F/TDF



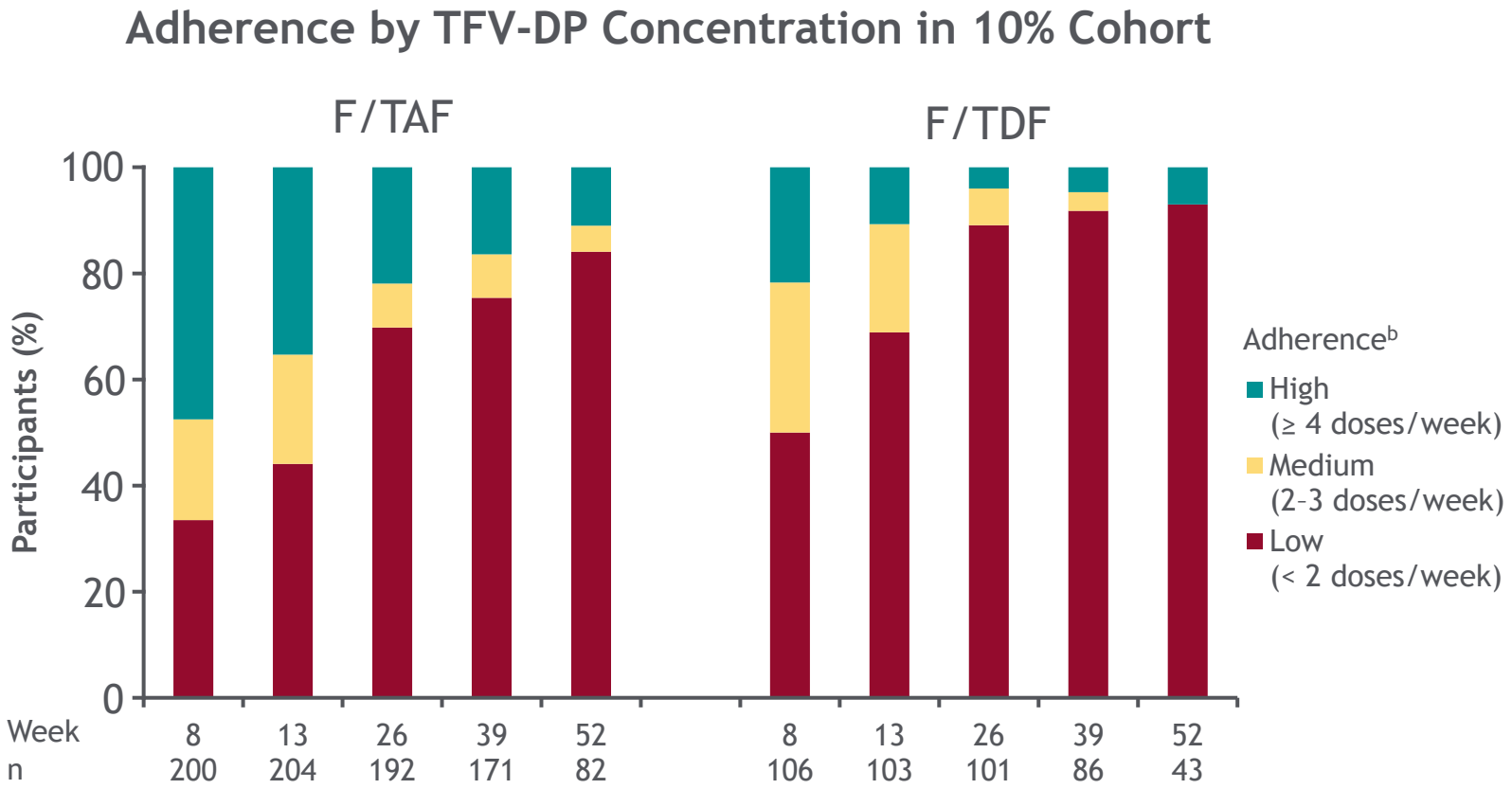
LEN reduced HIV infections by 100% in PURPOSE 1 and by 89% in PURPOSE 2 compared with daily oral F/TDF; in PURPOSE 1, F/TAF was not numerically different from F/TDF

[a]HIV IRR vs F/TDF was assessed using an exact conditional Poisson regression model (LEN, due to zero infections). [b]HIV IRR vs F/TDF was assessed using Poisson regression.

PURPOSE 1 Adherence to Injections Was Much Higher vs Oral F/TAF and F/TDF

Injections were on time[a] for:

- **91.5% (4545/4967) at Week 26**
- **92.8% (2025/2181) at Week 52**



Notably in the F/TAF group, there was a significantly lower likelihood of HIV infection associated with medium or high adherence compared with low adherence (odds ratio 0.11; 95% CI 0.012-0.49; *P* = 0.0006)

[a]Adherence to LEN was defined as on-time injections (< 28 weeks from the last injection), and participants who presented late required negative HIV testing to reinitiate study product, which included reloading with oral LEN or placebo. [b]Preselected 10% sample of participants assessed for TFV-DP concentrations in DBS (adherence cutoffs for F/TAF: low < 450, medium ≥ 450 to < 900, high ≥ 900 fmol/punches; and for F/TDF: low < 350, medium ≥ 350 to < 700, high ≥ 700 fmol/punch). **DBS**, dried blood spot; **TFV-DP**, tenofovir diphosphate.

PURPOSE 1 Pregnancies Were Common and Outcomes Similar to Expected Rates in the Population

Participants and Pregnancies, n (%)	LEN n = 2138	F/TAF n = 2137	F/TDF n = 1070
Participants with confirmed pregnancies	184	208	95
Confirmed pregnancies	193	219	98
Completed pregnancies	105 (54.4)	119 (54.3)	53 (54.1)
Ongoing pregnancies	88 (45.6)	100 (45.7)	45 (45.9)
Births[a]	55 (28.5)	45 (20.5)	21 (21.4)
Interrupted pregnancies	50 (25.9)	74 (33.8)	32 (32.7)
Induced abortion	30 (15.5)	40 (18.3)	20 (20.4)
Spontaneous miscarriage[b]	20 (10.4)	34 (15.5)	12 (12.2)

Expected spontaneous miscarriage rate:[1,2]

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

Available pregnancy outcomes were similar to those expected for the population[3]

[a]Completed uninterrupted pregnancies, which includes live births and 8 still births: 3 in the LEN group, 4 in the F/TAF group, and 1 in the F/TDF group. [b]Spontaneous miscarriage defined as occurring at < 20 weeks' gestation.

1. ACOG Committee on Practice Bulletins—Gynecology. *Obstet Gynecol*. 2018;132(5):e197-e207. **2.** Wilcox AJ, et al. *N Engl J Med*. 1988;319:189-94. **3.** Mugo NR, et al. *JAMA*. 2014;312(4):362-71.

LEN, F/TAF, and F/TDF Are Safe and Well Tolerated

PURPOSE 1

Adverse Event,[a]	LEN n = 2138	F/TAF n = 2137	F/TDF n = 1070
Any, n (%)	1631 (76)	1665 (78)	830 (78)
Grade ≥ 2	1111 (52)	1078 (50)	533 (50)
Grade ≥ 3	88 (4)	95 (4)	50 (5)
Serious AEs	59 (3)	85 (4)	35 (3)
AEs leading to discontinuation of study drug	5 (<1)[b]	2 (< 1)[c]	0
AEs occurring in ≥ 10% of participants, n (%)			
Headache	285 (13)	352 (16)	155 (14)
Urinary tract infection	307 (14)	305 (14)	163 (15)
Genitourinary chlamydia infection	300 (14)	317 (15)	129 (12)
Upper respiratory tract infection	271 (13)	274 (13)	121 (11)
Nausea	144 (7)	234 (11)	142 (13)
Vomiting	125 (6)	235 (11)	107 (10)
Laboratory abnormalities, n with ≥ 1 post-baseline result	2126	2113	1054
Any grade ≥ 1, n (%)	1929 (91)	1904 (90)	959 (91)

6 deaths, all in the F/TAF group;[d] none related to study drug per investigator

PURPOSE 2

Adverse Event,[a]	LEN n = 2183	F/TDF n = 1088
Any, n (%)	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)[e]
AEs occurring in ≥ 5% of participants, n (%)		
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, n with ≥ 1 post-baseline result	2153	1071
Any grade ≥ 1, n (%)	1822 (85)	937 (87)

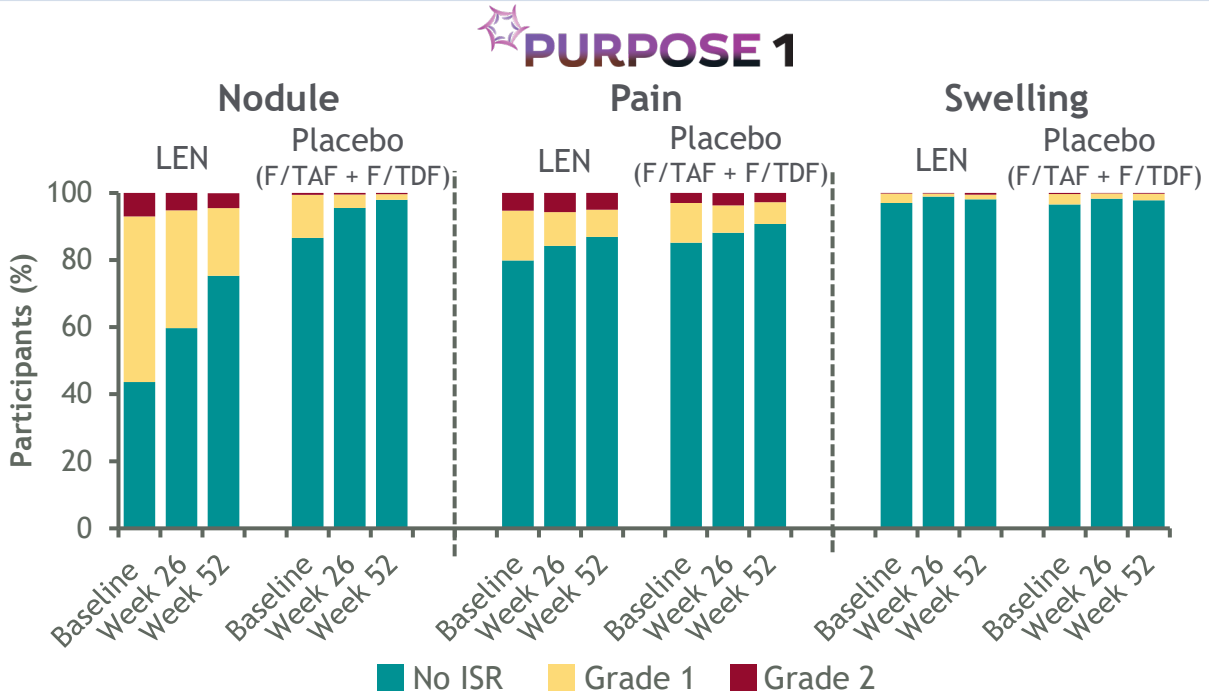
4 deaths in the LEN group and 2 deaths in the F/TDF group;[f] none related to study drug per investigator

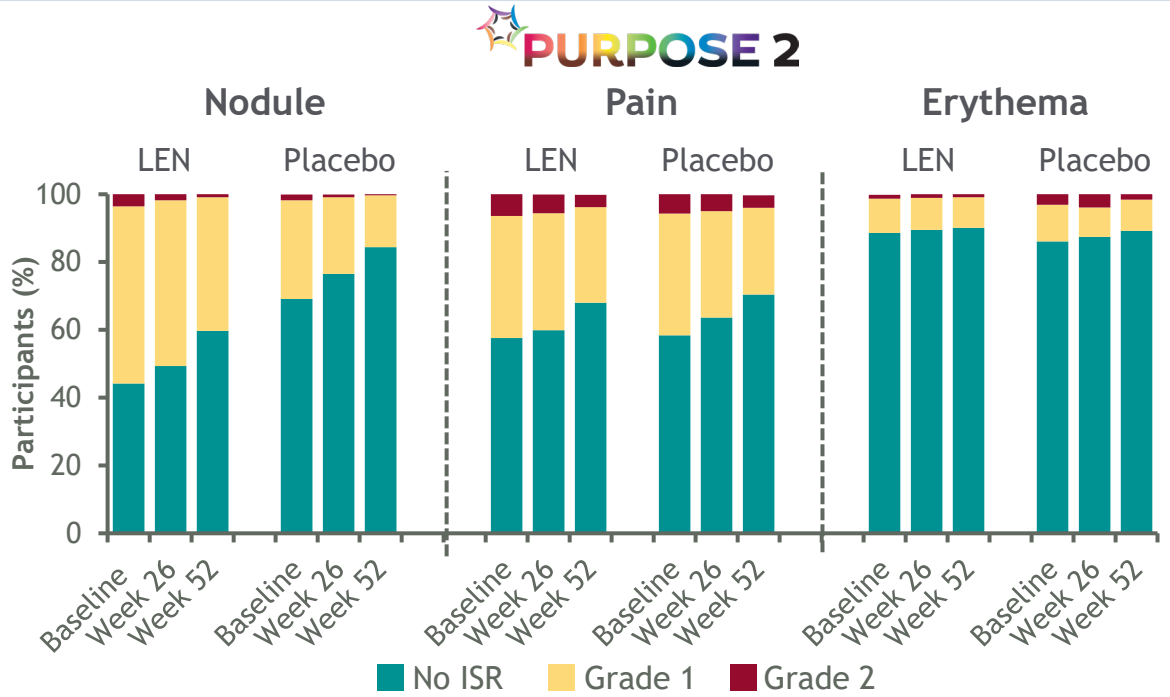
AEs were consistent with prior LEN, F/TAF and F/TDF trials.[1-4] In PURPOSE 2, the frequency of AEs and laboratory abnormalities was similar between arms, with the exception of changes in eGFR (significantly different at Week 26 and Week 52).[g]

[a]AEs are treatment emergent in persons who received at least 1 dose of study drug; AEs exclude 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 AEs, Version 2.1. [b]n = 1 for each of: nausea, decreased creatinine renal clearance, increased hepatic enzyme, spontaneous miscarriage, suicide attempt/major depression. [c]n = 1 for each of: suicide attempt/depressive symptoms/drug overdose, angioedema. [d]Asphyxia secondary to strangulation, non-accidental burns, knife stab to chest, hemorrhage due to traffic accident, autopsy-confirmed ischemic cardiomyopathy, and ovarian cancer. [e]AEs leading to discontinuation of study drug in > 1 participant in any group: decreased creatinine renal clearance (2 participants in the F/TDF group). [f]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. [g]PURPOSE 2: 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 ($P = 0.0024$). In PURPOSE 1, adherence to F/TDF was too low to impact eGFR. **AE**, adverse event; **ISR**, injection-site reaction. **1.** Gupta SK, et al. *Lancet HIV*. 2023;10(1):e15-e23. **2.** Ogbuagu O, et al. *Lancet HIV*. 2023;10(8):e497-e505. **3.** Mayer KH, et al. *Lancet*. 2020;396:239-54. **4.** Baeten JM, et al. *N Engl J Med*. 2012;367:399-410.

Injection-Site Reaction Frequency and Grade 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. **The frequency of ISRs, including nodules, decreased with subsequent doses (also observed with HIV treatment[1]).**





In PURPOSE 1, among 25,329 LEN/placebo injections, only 4 ISRs led to discontinuation (all LEN)
In PURPOSE 2, among 15,239 LEN/placebo injections, only 29 ISRs led to discontinuation (LEN, 26; F/TDF, 3)

AEs coded according to Medical Dictionary for Regulatory Activities, Version 27.0. Grade 1 and 2 ISRs are shown. In PURPOSE 1: LEN n: baseline, 2138; Week 26, 1930; Week 52, 862. Placebo (F/TAF + F/TDF) n: baseline, 3206; Week 26, 2883; Week 52, 1274; SC nodules, injection-site pain, and swelling were the most commonly reported ISRs, occurring in 63.8%, 31.2%, and 4.4% of participants in the LEN group, respectively, vs 16.6%, 23.7%, and 5.4% of participants given placebo injections; Grade 3 ISRs in the LEN group: n = 1 nodule; F/TDF group: n = 1 pain. In PURPOSE 2, LEN n: baseline, 2183; Week 26, 1859; Week 52, 744; Placebo n: baseline, 1088; Week 26, 946; Week 52, 379; SC 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 3 ISRs in the LEN group: n = 4 pain, n = 3 erythema; F/TDF group: n = 1 pain. **1.** Kumar P, et al. Abstract EPB184 presented at the 24th International AIDS Conference, July 29 to August 2, 2022; Montreal, Canada.

PURPOSE 1 and 2 Data Summary

	PURPOSE 1	PURPOSE 2
Study population	**Cisgender women**	**CGBMSM, TGW, TGM, and GNB people who have sex with partners assigned male sex at birth**
Baseline demographics and clinical characteristics	**Balanced** across randomized groups	**Balanced** across randomized groups
Efficacy	LEN HIV prevention efficacy was **superior** to both background HIV incidence and daily oral F/TDF **Zero HIV infections** among 2134 participants receiving LEN LEN reduced HIV infections by **100%** compared with bHIV incidence and daily oral F/TDF	LEN HIV prevention efficacy was **superior** to both background HIV incidence and daily oral F/TDF **Two HIV infections** among 2179 participants receiving LEN LEN reduced HIV infections by **96%** compared with bHIV incidence and by 89% compared with daily oral F/TDF
Safety	LEN and F/TAF were **safe and well tolerated** Most common ISRs: SC nodules, injection-site pain, and **swelling** **ISR frequency and grade diminished** with subsequent injections (also observed in other studies[1-3]) **Adherence to F/TDF was too low to impact eGFR**	LEN and F/TDF were **safe and well tolerated** Most common ISRs: SC nodules, injection-site pain, and **erythema** **ISR frequency and grade diminished** with subsequent injections (also observed in other studies[1-4]) LEN increased eGFR while F/TDF decreased eGFR; this **difference was more pronounced** in PURPOSE 2 vs PURPOSE 1

Twice-yearly LEN offers an efficacious, safe, and well-tolerated choice for HIV prevention in the most globally racially, ethnically, and gender-diverse Phase 3 program conducted to date. All trial participants are being offered open-label LEN.

1. Segal-Maurer S, et al. *N Engl J Med*. 2022;386:1793-1803. **2.** Landovitz RJ, *N Engl J Med*. 2021; 385(7):595-608. **3.** Delany-Moretlwe S, et al. *Lancet*. 2022; 399:1779-1789. **4.** Bekker L-G, et al. *N Engl J Med*. 2024;391:1179-92.

PURPOSE 1

First to intentionally include pregnant and lactating people in Phase 3 clinical trials

PURPOSE 2

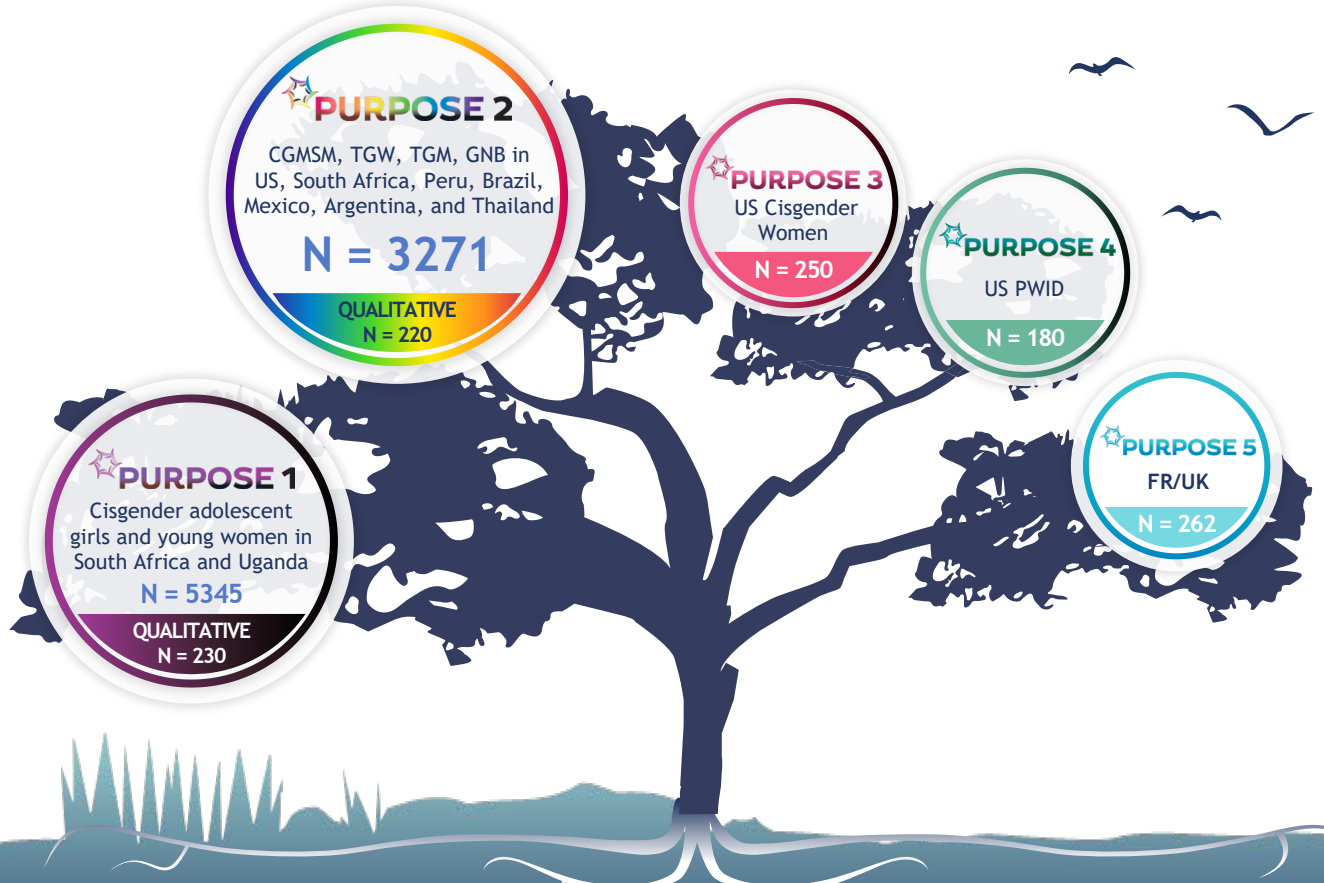
Intentionally focusing on CGMSM and TGW of color and first to include TGM and GNB people

PURPOSE 1 and 2: First to include adolescents in Phase 3 clinical trials

- Partnerships
- Voice of the PWBP and Community (G-CAGs)
- Person-Centric Design
- Diversity, Equity, and Inclusion

Changing where, with whom, and how we work so we can end the HIV epidemic for everyone, everywhere

PURPOSE 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

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

- Royalty-free, voluntary licensing agreements are in place with 6 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 United States

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 Oct 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 Oct 4, 2024).
HTE, heavily treatment-experienced.

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PURPOSE

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