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Yeztugo® (lenacapavir) PURPOSE 2 Study

This document is in response to your request for information regarding Yeztugo® (lenacapavir [LEN]) and the PURPOSE 2 study.

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Summary

Clinical Data From the PURPOSE 2 Study

PURPOSE 2 is an ongoing, phase 3, double-blind, randomized study evaluating the efficacy and safety of twice-yearly SUBQ LEN and once-daily oral FTC/TDF for HIV-1 PrEP in 3265 cisgender gay, bisexual, and other men; TGW; TGM; and GNB individuals in Argentina, Brazil, Mexico, Peru, South Africa, Thailand, and the US who have condomless receptive anal sex with partners assigned male at birth. Study participants were randomly assigned in a 2:1 ratio to receive twice-yearly SUBQ LEN or daily oral FTC/TDF.[1]

PURPOSE 2 met its key efficacy endpoints at the prespecified primary analysis, demonstrating superiority of LEN over bHIV (incidence expected in the absence of PrEP) and FTC/TDF. LEN reduced HIV incidence by 96% compared with bHIV incidence (primary endpoint; IRR, 0.04; 95% CI: 0.01–0.18; $P<0.001$) and by 89% compared with daily oral FTC/TDF (secondary endpoint; IRR, 0.11; 95% CI: 0.02–0.51; $P=0.002$).[1]

- There were 2 incident cases among 2179 participants in the LEN group (incidence, 0.1 per 100 PY).
- There were 9 incident cases among 1086 individuals in the FTC/TDF group (incidence, 0.93 per 100 PY).

At the end of the RBP, there was 1 additional incident case in the LEN group (incidence, 0.11 per 100 PY) and 3 additional incident cases in the FTC/TDF group (incidence, 0.92 per 100 PY).[2]

At OLE Week 52, there was 1 new incident case of HIV in a participant in the continuous LEN group, with a cumulative HIV incidence (95% CI) of 0.09 (0.02–0.22) per 100 PY in the continuous LEN group. There were no cases of HIV acquisition in the LEN switch group.[3]

At the primary analysis, the overall frequencies of non-ISR AEs and laboratory abnormalities were similar between groups, with the exception of changes in eGFR. Most ISRs were mild to moderate in severity and were reported in 1816 participants (83.2%) who received SUBQ LEN and 756 participants (69.5%) who received SUBQ LEN placebo injections.[1]

At the end of the RBP, no new safety concerns were noted, no additional discontinuations due to ISRs occurred, and the incidence and severity of ISRs in the LEN group were generally similar to those observed at the primary analysis.[2]

Through OLE Week 52, safety outcomes were similar between participants in the continuous LEN group and those in the LEN switch group.[3]

Clinical Data From the PURPOSE 2 Study

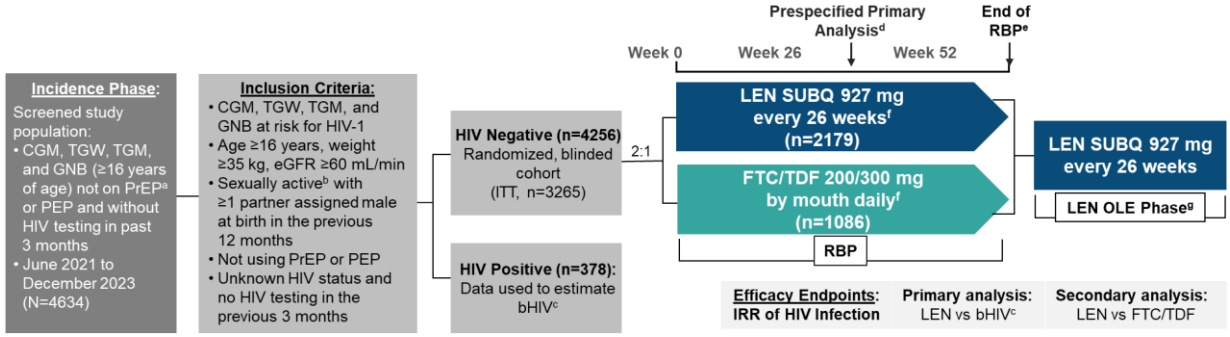
Study Design and Demographics

PURPOSE 2 (NCT04925752) is an ongoing, phase 3, double-blind, randomized study evaluating the efficacy and safety of twice-yearly SUBQ LEN and once-daily oral FTC/TDF for HIV-1 PrEP in cisgender gay, bisexual, and other men; TGW; TGM; and GNB individuals aged ≥16 years in Argentina, Brazil, Mexico, Peru, South Africa, Thailand, and the US who have condomless receptive anal sex with partners assigned male at birth (N=3265). Eligible participants were tested for HIV at screening, and those who tested negative were randomly assigned in a 2:1 ratio to SUBQ LEN every 26 weeks + daily oral FTC/TDF placebo (n=2179) or SUBQ LEN placebo every 26 weeks + daily oral FTC/TDF (n=1086; Figure 1). Additional testing was performed with samples from participants who tested positive for HIV at screening to determine the recency of the HIV infection, and these data were used to estimate the bHIV that would be expected without PrEP.[1]

Key inclusion criteria in the randomized phase of the study included the following: negative results on point-of-care fourth-generation Ag/Ab test and central laboratory fourth-generation Ag/Ab test (if positive, was confirmed by an HIV-1/2 Ab differentiation assay), qualitative HIV-1 RNA test (lower limit of quantification, 20 c/mL), eGFR ≥60 mL/min, and body weight ≥35 kg at screening. Individuals were excluded if they had prior use of HIV PrEP (including FTC/TDF or FTC/TAF) or HIV PEP in the past 3 months or any prior use of long-acting injectable HIV PrEP.[1,4] The primary efficacy endpoint was the incidence of HIV among randomized participants.[1]

On September 11, 2024, an external independent data monitoring committee concluded that the prespecified efficacy criteria for stopping the blinded portion of the trial had been met based on the interim results, and (per the trial protocol) the interim analysis became the primary analysis. All participants were offered the option to receive open-label SUBQ LEN on September 25, 2024.[1]

Figure 1. PURPOSE 2: Study Design[1,2,4]



[a]Included oral PrEP use within the last 12 weeks or any prior use of long-acting injectable forms of PrEP.
[b]Condomless receptive anal sex with ≥1 partner in the previous 12 months and met ≥1 of the following criteria: condomless receptive anal sex with ≥2 partners in the previous 12 weeks; history of syphilis, rectal gonorrhea, or rectal chlamydia in the previous 24 weeks; self-reported use of stimulants with sex in the previous 12 weeks.
[c]The bHIV was the incidence of HIV expected without PrEP that would be anticipated in a placebo group. A total of 45 participants (11.9%) were classified as having recently acquired HIV.
[d]The determination of efficacy was based on the prespecified interim analysis when 50% of RBP participants completed 52 weeks of follow-up. Based on results, the study arms were unblinded, and the interim analysis became the primary analysis (per protocol).
[e]Participants who declined LEN OLE were offered up to 78 weeks of open-label FTC/TDF if they were on blinded LEN in RBP.
[f]All participants received a loading dose of oral LEN 600 mg or matching placebo on Days 1 and 2. Participants in the LEN group received placebo FTC/TDF, and participants in the FTC/TDF group received placebo SUBQ LEN. These participants were included in the full analysis set for the primary efficacy analysis, and additional participants were included in the safety analysis.
[g]Those who received FTC/TDF during the RBP and continued to the OLE phase received oral LEN 600 mg on Days 1 and 2 of the OLE.

A total of 3271 participants were randomly assigned and received ≥1 dose of study drug; 6 participants were diagnosed with HIV on Day 1 and were excluded from the efficacy analysis (mITT, n=3265). Baseline demographics were balanced between RBP groups at the primary analysis (Table 1).[1]

Table 1. PURPOSE 2: Select Baseline Demographics and Characteristics[1]

Key Demographics and Characteristics		LEN (n=2183)	FTC/TDF (n=1088)
Age	Median (range), years	28 (17–74)	29 (17–73)
	16 to ≤25 years, n (%)	752 (34.4)	344 (31.6)
Country, n (%)	Brazil	769 (35.2)	396 (36.4)
	United States	440 (20.2)	235 (21.6)
	Peru	309 (14.2)	138 (12.7)
	Thailand	250 (11.5)	139 (12.8)
	South Africa	246 (11.3)	112 (10.3)
	Argentina	161 (7.4)	64 (5.9)
	Mexico	8 (0.4)	4 (0.4)
Race or ethnicity, n/N (%)	Hispanic or Latine	1378/2182 (63.2)	675/1088 (62)
	Black[a]	811/2175 (37.3)	420/1086 (38.7)
	White	722/2175 (33.2)	344/1086 (31.7)
	Indigenous or Indigenous ancestry[b]	341/2175 (15.7)	156/1086 (14.4)
	Asian	269/2175 (12.4)	144/1086 (13.3)
	Other and other multiracial[c]	32/2175 (1.5)	22/1086 (2)

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Key Demographics and Characteristics		LEN (n=2183)	FTC/TDF (n=1088)
Gender identity, n (%)	CGM	1697 (77.7)	846 (77.8)
	TGW	315 (14.4)	161 (14.8)
	GNB[d]	136 (6.2)	63 (5.8)
	TGM	29 (1.3)	14 (1.3)
	Other[e]	6 (0.3)	4 (0.4)
Sexually transmitted infections,[f] n (%)	*Chlamydia trachomatis*	253 (11.6)	126 (11.6)
	Neisseria gonorrhea	193 (8.8)	115 (10.6)
	Syphilis	84 (3.8)	43 (4)
No history of HIV test, n (%)		597 (27.3)	306 (28.1)
Any history of PrEP use, 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)

[a]Included all participants who identified as Black/of Black ancestry: Black, Black/White, Black/Pardo (a specific racial category in Brazil), Black/Brown (Brazil), Black/Colored (a specific racial category in South Africa), Black/American Indian or Alaskan Native, Black/Asian, and Black/Native Hawaiian or Pacific Islander.
[b]Included all participants who identified as American Indian or Alaskan Native, Native Hawaiian or Pacific Islander, Asian/Native Hawaiian or Pacific Islander, White/Native Hawaiian or Pacific Islander, and White/American Indian or Alaskan Native.
[c]Included all participants who identified as Asian/White, Colored (South Africa), Pardo (Brazil), White/Brown (Brazil), multiracial any other, and not multiracial other.
[d]Included 122 participants (89.7%) in the LEN group and 53 participants (84.1%) in the FTC/TDF group assigned male at birth.
[e]Included individuals who identified as Travesti (LEN, n=3; FTC/TDF, n=3) or as an "other" gender (LEN, n=3; FTC/TDF, n=1).
[f]*Chlamydia trachomatis* and *Neisseria gonorrhea* were diagnosed based on pharyngeal, rectal, and urethral (urine) samples tested by central and local laboratories. Syphilis was diagnosed by blood testing performed locally using local testing protocols.

Efficacy

Primary analysis[1]

In total, 3220 participants had ≥1 post-randomization HIV-1 test, resulting in 2905 PY of follow-up for calculations of incident HIV. The prespecified primary analysis was conducted when 50% of participants had completed ≥52 weeks of follow-up.

The bHIV in the screened population was 2.37 per 100 PY (95% CI: 1.65–3.42; Figure 2). In the LEN group, there were 2 incident HIV cases (0.1 per 100 PY; 95% CI: 0.01–0.37) that occurred 13 and 26 weeks after the first dose. Both participants had LEN concentrations above the IQ4 (15.5 ng/mL) at the time of diagnosis; no delayed diagnosis was revealed by retrospective HIV-1 RNA viral load testing, and both participants developed the N74D capsid resistance mutation. There were 9 incident HIV cases (0.93 per 100 PY; 95% CI: 0.43–1.77) in the FTC/TDF group; these participants had low/no adherence (determined through measurements of TFV-DP levels in DBS) or had documented discontinuation of FTC/TDF >10 days prior to diagnosis, and 1 participant was found to have an M184V resistance mutation.

PURPOSE 2 met its key efficacy endpoints, demonstrating superiority of twice-yearly SUBQ LEN over bHIV and daily oral FTC/TDF. LEN reduced HIV incidence by 96% compared with bHIV incidence (primary endpoint; IRR, 0.04; 95% CI: 0.01–0.18; $P<0.001$) and by 89% compared with daily oral FTC/TDF (secondary endpoint; IRR, 0.11; 95% CI: 0.02–0.51; $P=0.002$; Figure 3).

Figure 2. PURPOSE 2 Primary Analysis: Incidence of HIV-1 (mITT Population)[1]

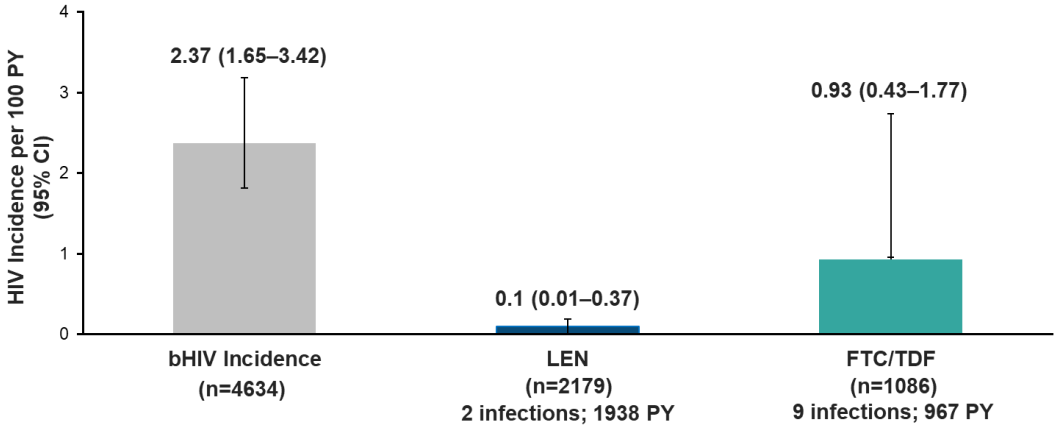
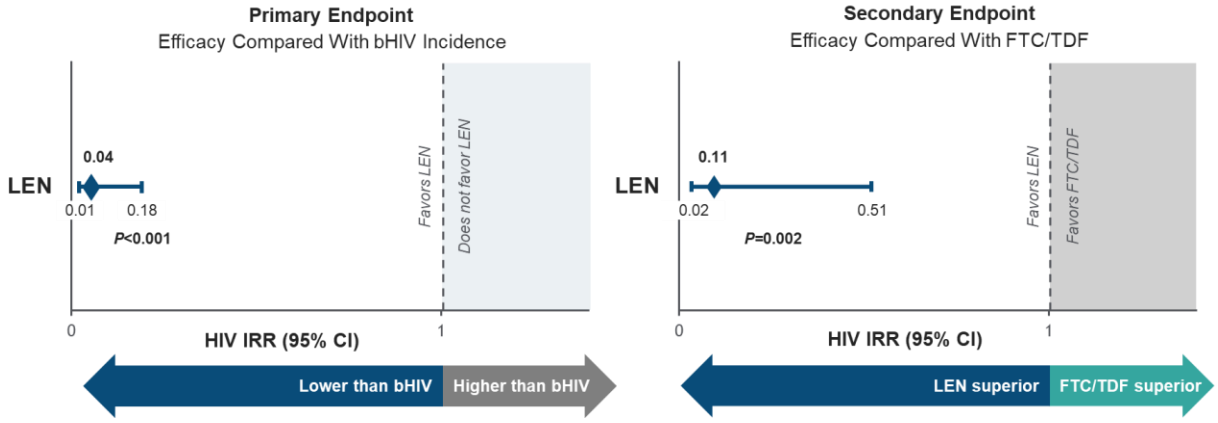


Figure 3. PURPOSE 2 Primary Analysis: Primary and Secondary Endpoints (mITT Population)[1]



Retention and adherence rates[1]

The overall study retention rate was high and was similar between treatment groups: Week 26, 94.4% (2834/3001); Week 52, 93.3% (1191/1277); and Week 104, 91.3% (63/69).

Adherence was high, and injections were administered on time (ie, within 28 weeks of prior injection) in 91% of participants (2606/2864) at Week 26 and in 92.8% of participants (1016/1095) at Week 52. In the FTC/TDF group, TFV-DP concentrations in DBS consistent with high adherence (≥4 pills per week) were observed in 82% at Week 8, 67% at Week 26, and in 62% at Week 52.

End-of-RBP efficacy analysis

The follow-up analysis conducted at the end of the RBP included all data from the RBP and follow-up after the first dose of open-label PrEP administered after early discontinuation of study drug during the RBP or after stopping any PrEP during the study and on or before the first dose of open-label LEN.[2]

Cumulatively, there were 3 incident HIV cases (0.11 per 100 PY; 95% CI: 0.02–0.31) in the LEN group after 2843 PY of follow-up, including 1 new HIV case; there were 12 incident cases (0.92 per 100 PY; 95% CI: 0.48–1.61) in the FTC/TDF group after 1305 PY of follow-up, including 3 new HIV cases.[2]

Through the end of the RBP, an additional LEN participant who had acquired HIV-1 had Q67H and K70R resistance mutations.[5] This participant in the LEN group was diagnosed with HIV at Week 52 using standard HIV testing (central Ag/Ab tests were positive, rapid Ag/Ab tests were negative, and HIV-1/2 Ab differentiation was negative; HIV-1 RNA: 2,020,000 c/mL); there was no evidence of delayed diagnosis (retrospective HIV-1 RNA testing showed no viremia at Week 39 prior to seroconversion). This participant was a young, gender-diverse person who had a history of rectal chlamydia at screening and Week 26 and was diagnosed with rectal gonorrhea at Week 26. They had all LEN injections on time, and LEN levels were generally within the range noted within a subset of study participants who underwent PK analysis. Their LEN concentration at HIV-1 diagnosis was 14.2 ng/mL (IQ4, 15.5 ng/mL; Week 56 level was >95th percentile of the subset of participants in PK analysis).[2]

OLE Week 52 efficacy and adherence analysis[3]

Of the participants who completed the RBP, 95% continued LEN or switched to LEN from FTC/TDF in the OLE phase. An efficacy analysis was conducted when 99% of participants reached OLE Week 52 and included 2183 participants in the continuous LEN group (4409 PY on LEN with a median follow-up of 117 weeks) and 827 participants who switched to LEN in the OLE phase (978 PY on LEN with a median follow-up of 65 weeks).

Through OLE Week 52, there was 1 new case of HIV acquisition at OLE Week 39 (HIV-1 RNA=243,000 c/mL) in a participant in the continuous LEN group. This participant was a gender-diverse person with a history of syphilis, rectal chlamydia at RBP Week 39, and rectal gonorrhea at RBP Week 52 and OLE Week 39. The participant received all LEN injections on time and had LEN concentrations above the IQ4 at most assessments; diagnosis was made via standard HIV testing, and the capsid mutation Q67H was present at OLE Week 39. The cumulative incidences of HIV acquisition at OLE Week 52 were 4 cases in the continuous LEN group (n=2179; incidence, 0.09 per 100 PY; 95% CI: 0.02–0.22) and no cases in the LEN switch group (n=825; incidence, 0; 95% CI: 0–0.38). The combined HIV incidence (95% CI) among participants who received LEN in the RBP plus those in the LEN switch group was 0.07 (0.02–0.18) per 100 PY.

Adherence to open-label LEN was high in both groups, with on-time injections (≤28 weeks after the last injection) in 95% of participants in the continuous LEN group and 96% of those in the LEN switch group at the second OLE injection at OLE Week 26, and in 90% and 92%, respectively, at the third OLE injection at OLE Week 52.

Safety

Primary analysis safety results[1]

Overall, the frequencies of non-ISR AEs and laboratory abnormalities were similar between groups (Table 2), except for changes in eGFR, with a median (IQR) change from baseline to Week 26 of +1.2 (-8 to +10.9) mL/min in the LEN group and -3 (-12.4 to +6.5) mL/min in the FTC/TDF group (P<0.001) and a median (IQR) change from baseline to Week 52 of +0.6 (-10.3 to +10.8) mL/min in the LEN group and -2.9 (-13.8 to +7.4) mL/min in the FTC/TDF group (P=0.002). There were 4 deaths (0.2%) in the LEN group (each, n=1: cerebrovascular accident and pulmonary thromboembolism, car collision, sudden death with an undetermined cause, and suicide) and 2 (0.2%) in the FTC/TDF group (each, n=1:

intracranial hemorrhage and undetermined cause); none were deemed related to study drug by investigator.

Table 2. PURPOSE 2: Safety Summary of Non-ISR AEs and Laboratory Abnormalities[1]

Non-ISR AEs, n (%) or n/N (%)		Primary Analysis	
		LEN (n=2183)	FTC/TDF (n=1088)
Any-grade AEs		1607 (73.6)	803 (73.8)
Grade ≥2		1173 (53.7)	594 (54.6)
Grade ≥3		91 (4.2)	65 (6)
SAEs		71 (3.3)	43 (4)
AEs that led to study drug discontinuation[a]		7 (0.3)	7 (0.6)
AEs in ≥5% of participants	Rectal chlamydia infection	289 (13.2)	128 (11.8)
	Oropharyngeal gonococcal infection	283 (13)	119 (10.9)
	Rectal gonococcal infection	233 (10.7)	99 (9.1)
	Upper respiratory tract infection	148 (6.8)	77 (7.1)
	Diarrhea	146 (6.7)	75 (6.9)
	Influenza	120 (5.5)	66 (6.1)
	Headache	119 (5.5)	76 (7)
	Latent syphilis	114 (5.2)	44 (4)
	Nausea	89 (4.1)	67 (6.2)
Any Grade ≥1 laboratory abnormality[b]		1822/2153 (84.6)	937/1071 (87.5)

[a]Decreased renal CrCl was the only non-ISR AE that led to study drug discontinuation in >1 participant in either group (FTC/TDF, n=2 [0.2%]).
[b]Included participants with ≥1 post-baseline result.

Overall, 10,094 SUBQ LEN and 5145 SUBQ LEN placebo injections were administered, and ISRs were reported in 1816 participants (83.2%) who received LEN and 756 participants (69.5%) in the FTC/TDF group who received placebo injections. Most ISRs were mild to moderate in severity, and nodules, pain, and erythema were the most common ISRs (coded according to MedDRA v27.0). Nodules were reported more frequently in the LEN group than in the placebo injection group (63.4% vs 39.2%, respectively), with a median (IQR) duration of 183 (89–274) days in the SUBQ LEN group and 64 (19–98) days in the placebo injection group. The median (IQR) duration of induration was 84 (8–190) days in the SUBQ LEN group and 8 (5–57) days in the placebo injection group. The incidence of pain was similar between groups (SUBQ LEN, 56.4%; placebo injection, 53.4%). There were no reports of keloid formation. Overall, the frequency and severity of ISRs decreased over time. AEs of ISRs led to study drug discontinuation in 29 participants (LEN, n=26 [1.2%]; FTC/TDF, n=3 [0.3%]).

End-of-RBP safety results[2]

Through the end of the RBP, no new safety concerns were noted, and no additional discontinuations due to ISRs occurred (Table 3). The incidence and severity of ISRs were generally similar to those observed in the primary analysis (Figure 4).

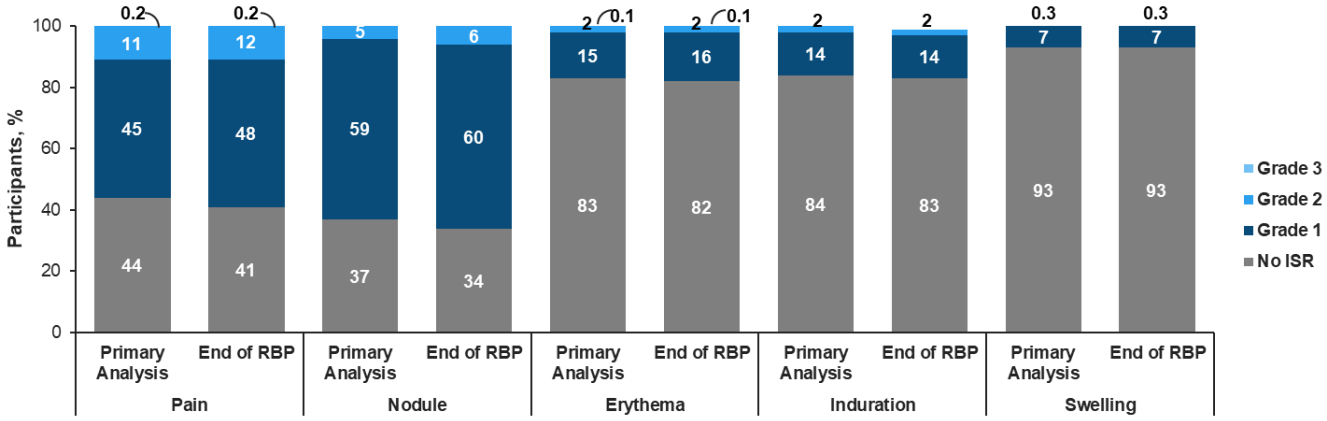
Table 3. PURPOSE 2 End-of-RBP Analysis: Safety Outcomes[2]

Safety Outcomes, n (%)	End-of-RBP Analysis
	LEN (n=2183)
Any-grade AEs (excluding ISRs)	1721 (79)
Grade ≥3 AEs	119 (5)
SAEs	96 (4)
AEs that led to LEN discontinuation	7 (<1)

Safety Outcomes, n (%)		End-of-RBP Analysis LEN (n=2183)
AEs in ≥10% of participants (excluding ISRs)	Anal chlamydia infection	351 (16)
	Oropharyngeal gonococcal infection	344 (16)
	Anal gonococcal infection	288 (13)
ISRs		1851 (85)
Grade 2 ISRs		390 (18)
Grade 3 ISRs		14 (1)
ISRs that led to LEN discontinuation		26 (1)

Note: All AEs were coded according to MedDRA v28.0.

Figure 4. PURPOSE 2 Primary and End-of-RBP Analyses: Severity of ISRs[2a]



[a]Included ISRs that occurred in ≥100 participants.

OLE Week 52 safety results[3]

Through OLE Week 52, safety outcomes were similar between participants in the continuous LEN group and those in the LEN switch group (Table 4).

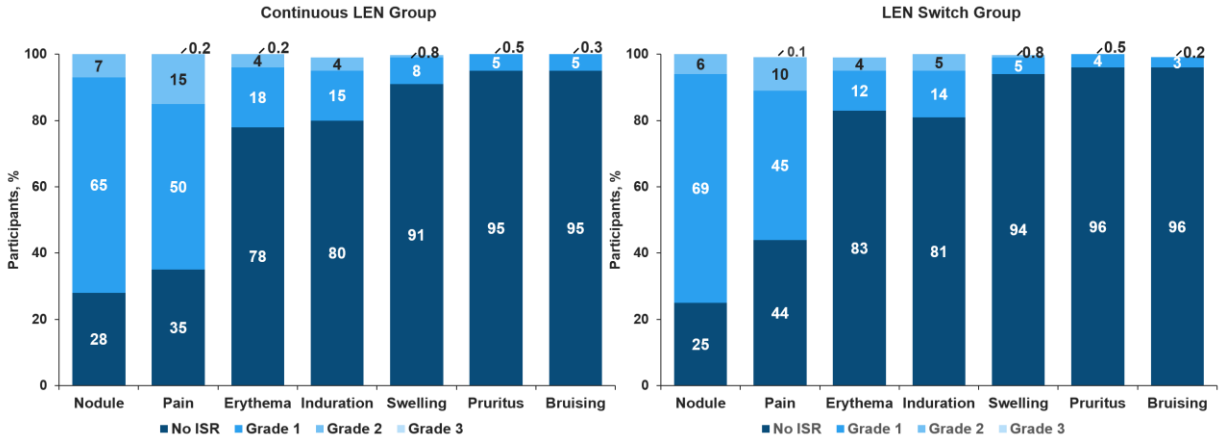
Table 4. PURPOSE 2 OLE Week 52 Analysis: Safety Outcomes[3]

Safety Outcomes, n (%)		OLE Week 52 Analysis	
		Continuous LEN (n=2183)	LEN Switch (n=827)
Any-grade AEs (excluding ISRs)		1869 (86)	658 (80)
Grade ≥3 AEs		183 (8)	36 (4)
SAEs		148 (7)	27 (3)
AEs that led to LEN discontinuation		8 (<1)	0
AEs that occurred in ≥15% of participants (excluding ISRs)	Oropharyngeal gonococcal infection	551 (25)	146 (18)
	Anal chlamydia infection	551 (25)	137 (17)
	Anal gonococcal infection	465 (21)	124 (15)
ISRs		1922 (88)	745 (90)
Grade 2		524 (24)	172 (21)
Grade 3 (highest grade reported)		17 (1)	4 (<1)
Led to LEN discontinuation		27 (1)	0

Note: All AEs were coded according to MedDRA v28.0.

The incidence and severity of ISRs were similar between the continuous LEN and LEN switch groups through OLE Week 52 (Figure 5).

Figure 5. PURPOSE 2 OLE Week 52 Analysis: ISRs[3]



Note: Included ISRs that occurred in ≥100 participants who received LEN injections through OLE Week 52.

References

1. Kelley CF, Acevedo-Quinones M, Agwu AL, et al. Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons. *N Engl J Med.* 2025;392(13):1261-1276.
2. Cantos VD, Mngadi K, Supparatpinyo K, et al. Lenacapavir for PrEP: HIV-1 Incidence and Safety from PURPORSE 2 at the End of Randomized Blinded Phase [Presentation]. Paper presented at: 33rd Conference on Retroviruses and Opportunistic Infections (CROI); February 22-25, 2026; Denver, CO.
3. Losso M, Santos B, Lama JR, et al. High Efficacy of Twice-Yearly Subcutaneous Lenacapavir for PrEP Through 52 Weeks of Open-Label Extension in PURPOSE 2 [Presentation]. Paper presented at: The 26th International AIDS Conference (AIDS); July 26-31, 2026; Rio de Janeiro, Brazil.
4. ClinicalTrials.gov. Study to Assess the Effectiveness and Safety of Lenacapavir for Human Immunodeficiency Virus (HIV) Pre-Exposure Prophylaxis (PURPOSE 2). ClinicalTrials.gov Identifier: NCT04925752. Available at: https://clinicaltrials.gov/ct2/show/NCT04925752?term=purpose-2&draw=2&rank=1. Accessed: 22 December. Last Updated: 21 December. 2022.
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Abbreviations

Ab=antibody
AE=adverse event
Ag=antigen
bHIV=background HIV incidence
c/mL=copies per mL
CGM=cisgender men
DBS=dried blood spots
FTC=emtricitabine
GNB=gender nonbinary
IQ4=inhibitory quotient 4
IRR=incidence rate ratio
ISR=injection site reaction
LEN=lenacapavir
MedDRA=Medical Dictionary for Regulatory Activities
mITT=modified intent-to-treat
OLE=open-label extension
PEP=post-exposure prophylaxis
PK=pharmacokinetic(s)
PrEP=pre-exposure prophylaxis
PY=person-years
RBP=randomized blinded phase
SAE=serious adverse event
SUBQ=subcutaneous(ly)
TAF=tenofovir alafenamide
TDF=tenofovir disoproxil fumarate
TFV-DP=tenofovir diphosphate
TGM=transgender men
TGW=transgender women

Product Label

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FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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