GILEAD | Medical Information

Yeztugo® (lenacapavir) PURPOSE 1 Study

This document is in response to your request for information regarding Yeztugo® (lenacapavir [LEN]) and the PURPOSE 1 study.

The use of FTC/TAF for prevention of HIV-1 in individuals at risk of HIV-1 from receptive vaginal sex is investigational and has not been approved by any regulatory authority.

The use of FTC/TAF for prevention of HIV-1 in individuals at risk of HIV-1 from receptive vaginal sex is investigational and has not been approved by any regulatory authority. The full indication, important safety information, and boxed warning(s) are available at:
www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_pi;
www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi;
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Summary

Clinical Data: PURPOSE 1 Study

PURPOSE 1 is a phase 3 ongoing, double-blind, randomized study evaluating the efficacy and safety of twice-yearly, SUBQ LEN (n=2138) and once-daily oral FTC/TAF (n=2137) or FTC/TDF (active control; n=1070) for HIV-1 PrEP in 5345 cisgender women and adolescent girls (16–25 years old) across South Africa and Uganda.[1]

- At the primary analysis, a total of 55 incident HIV cases had occurred; no participants in the LEN group acquired HIV (1939 PY; incidence rate: 0 per 100 PY; 95% CI: 0–0.19), 39 HIV cases occurred in the FTC/TAF group (1932 PY; incidence rate, 2.02 per 100 PY; 95% CI: 1.44–2.76), and 16 occurred in the FTC/TDF group (949 PY; incidence rate, 1.69 per 100 PY; 95% CI: 0.96–2.74). The bHIV incidence in the screened population was 2.41 per 100 PY (95% CI: 1.82–3.19).[1]
- LEN significantly reduced the incidence rate of HIV by 100% compared with bHIV (IRR, 0; 95% CI: 0–0.04; *P*<0.001) and FTC/TDF (IRR, 0; 95% CI: 0–0.1; *P*<0.0001). [1,2]
- The incidence rate of HIV in the FTC/TAF group was not significantly different from bHIV (IRR, 0.84; 95% CI: 0.55–1.28; *P*=0.21), and there was no evidence of a meaningful difference in HIV incidence from FTC/TDF (IRR, 1.2; 95% CI: 0.67–2.14).[1]
- Through the end of the RBP, there were 79 incident HIV cases, comprised of 2 cases in the LEN group (2953 PY; incidence rate, 0.07; 95% CI: 0.01–0.25), 52 cases in the FTC/TAF group (2630 PY; incidence rate, 1.98; 95% CI: 1.48–2.59), and 25 in the FTC/TDF group (1291 PY; incidence rate, 1.94; 95% CI: 1.25–2.86).[3]
- At the primary analysis, LEN, FTC/TAF, and FTC/TDF were all generally well tolerated, with few discontinuations due to study drug-related AEs. The overall incidences of non-ISR AEs, including Grade ≥3 and serious AEs, were generally similar across treatment groups. Nausea and vomiting occurred at higher rates in the FTC/TAF and FTC/TDF groups than in the LEN group.[1]

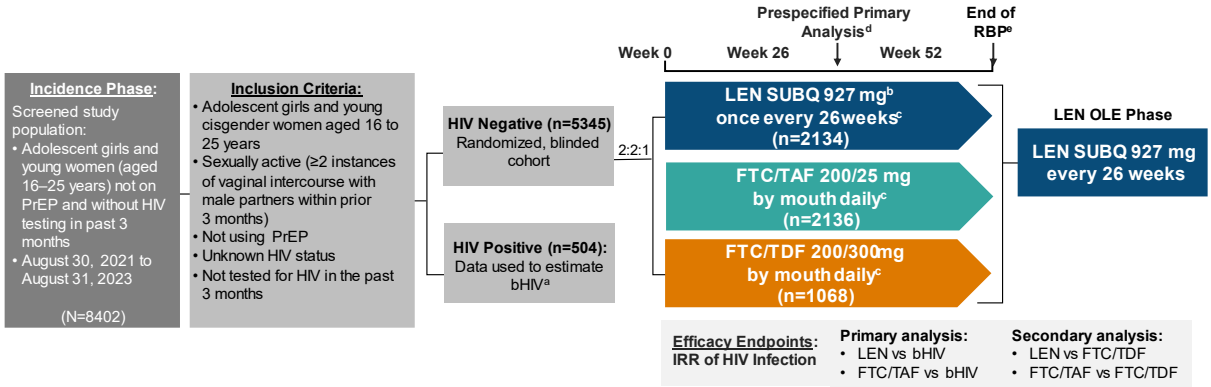
- ISRs were the most common AE in all groups and occurred at a higher rate with LEN than with placebo injections. ISRs were primarily Grade ≤2 and decreased in frequency over time. Discontinuations due to ISRs were rare, with 4 discontinuations in the LEN group and none in the groups that received placebo injections.[1] There were no new safety concerns with LEN through the end of the RBP.[3]

Clinical Data: PURPOSE 1 Study

Study Design and Demographics

PURPOSE 1 (NCT04994509) is an ongoing, phase 3, double-blind, randomized, active-controlled study evaluating the efficacy and safety of twice-yearly, SUBQ LEN and once-daily oral FTC/TAF for HIV-1 PrEP in cisgender women and adolescent girls across South Africa and Uganda. Additionally, a third group was assigned once-daily oral FTC/TDF, which served as the active control. Eligible women and adolescent girls were tested for HIV at screening, and those who tested negative were randomly assigned in a 2:2:1 ratio to receive LEN 927 mg SUBQ every 26 weeks, FTC/TAF 200/25 mg orally daily, or FTC/TDF 200/300 mg orally daily (Figure 1). Those who tested positive for HIV at screening were referred for care at a local center and their samples underwent additional testing to determine the recency of HIV; these data were used to estimate the bHIV that would be expected without PrEP. Participants who discontinued blinded study drug were given the option to take open-label FTC/TDF. Testing for HIV in the randomized cohort was conducted at Weeks 4, 8, and 13 and every 13 weeks thereafter.[1]

Figure 1. PURPOSE 1: Study Design[1,3,4]



[a]The bHIV was determined based on a cross-sectional incidence estimate derived from rates of recent HIV in 8094 screened participants; these participants were not followed longitudinally.
[b]All participants randomly assigned to receive LEN received an initial loading dose of LEN, which consisted of 600 mg (two 300-mg tablets) administered on Days 1 and 2.
[c]Participants in the LEN SUBQ group also received placebo FTC/TAF or placebo FTC/TDF (2:1), and participants in the FTC/TAF and FTC/TDF groups also received placebo LEN oral loading doses and placebo LEN SUBQ.
[d]The prespecified primary analysis was conducted when 50% of participants had completed ≥52 weeks of follow-up.
[e]Participants who were on blinded LEN in the RBP and declined open-label LEN were offered up to 78 weeks of open-label FTC/TDF.

A total of 5345 participants were randomly assigned and received ≥1 dose of study drug. Baseline characteristics at randomization among the three treatment groups were similar. Overall retention in the study was high and similar across treatment groups, with

4855/5020 participants (96.7%) completing 26 weeks of follow-up, 2439/2612 participants (93.4%) completing 52 weeks, and 39/43 participants (91%) completing 104 weeks.[1]

An independent committee determined that the planned interim efficacy analysis (when 50% of participants had completed ≥52 weeks of follow-up; data cutoff for clinical data, May 28, 2024, and data cutoff for laboratory data, May 29, 2024) met the prespecified criteria for stopping the RBP portion of the trial and became the primary analysis. Starting July 8, 2024, all participants were offered open-label LEN.[1]

Table 1. PURPOSE 1: Select Baseline Demographics[1]

Key Demographics and Characteristics		LEN (n=2138)	FTC/TAF (n=2137)	FTC/TDF (n=1070)
Age	Median (range), years	21 (16–25)	21 (16–26)	21 (16–25)
	16 or 17 years of age, n (%)	56 (2.6)	45 (2.1)	23 (2.1)
Black race, n (%)		2135 (99.9)	2136 (>99.9)	1068 (99.8)
Living with primary partner, n/N (%)		148/2136 (6.9)	132/2134 (6.2)	73/1069 (6.8)
Previous use of PrEP, n (%)		143 (6.7)	121 (5.7)	71 (6.6)
Previously tested for HIV, n (%)		1713 (80.1)	1731 (81)	860 (80.4)
Time since last HIV test, median (IQR), months		6.8 (4.7–11.5)	6.6 (4.8–11)	6.5 (4.6–11)
Sexually transmitted infections, 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)
Country, n (%)	South Africa	1809 (84.6)	1790 (83.8)	909 (85)
	Uganda	329 (15.4)	347 (16.2)	161 (15)

Efficacy

Primary and secondary endpoint analyses[1]

A total of 55 incident HIV cases occurred in the randomized cohort; no participants in the LEN group acquired HIV (1939 PY; incidence rate, 0 per 100 PY; 95% CI: 0–0.19), 39 HIV cases occurred in the FTC/TAF group (1932 PY; incidence rate, 2.02 per 100 PY; 95% CI: 1.44–2.76), and 16 occurred in the FTC/TDF group (949 PY; incidence rate, 1.69 per 100 PY; 95% CI: 0.96–2.74). The bHIV in the screened population was 2.41 per 100 PY (Figure 2).[1]

LEN significantly reduced the incidence rate of HIV by 100% compared with both the bHIV incidence rate (IRR, 0; 95% CI: 0–0.04; $P<0.001$) and the rate with FTC/TDF (IRR, 0; 95% CI: 0–0.1; $P<0.0001$). [1,2] The incidence rate of HIV in the FTC/TAF group did not significantly differ from the bHIV incidence rate (IRR, 0.84; 95% CI: 0.55–1.28; $P=0.21$), and there was no evidence of difference in the incidence of HIV with FTC/TDF (IRR, 1.2; 95% CI: 0.67–2.14).[1]

Figure 2. PURPOSE 1 Primary Analysis: Incidence of HIV[1]

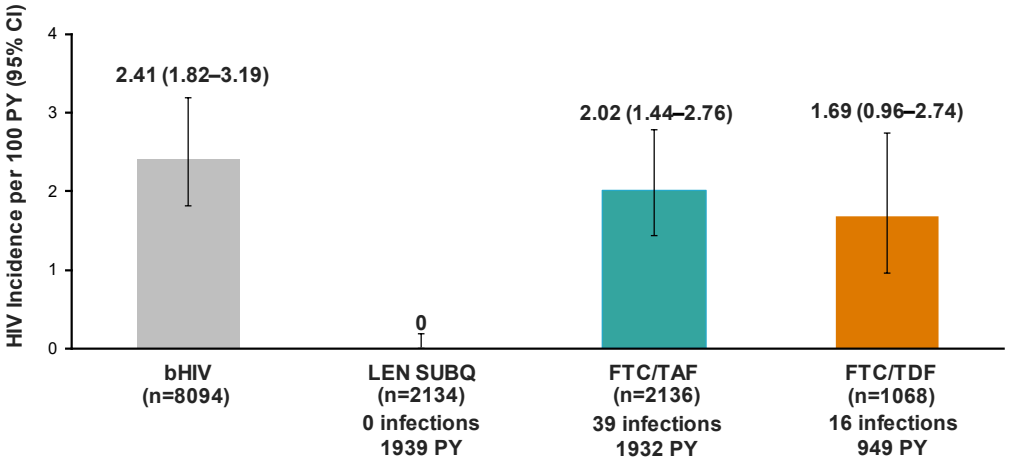
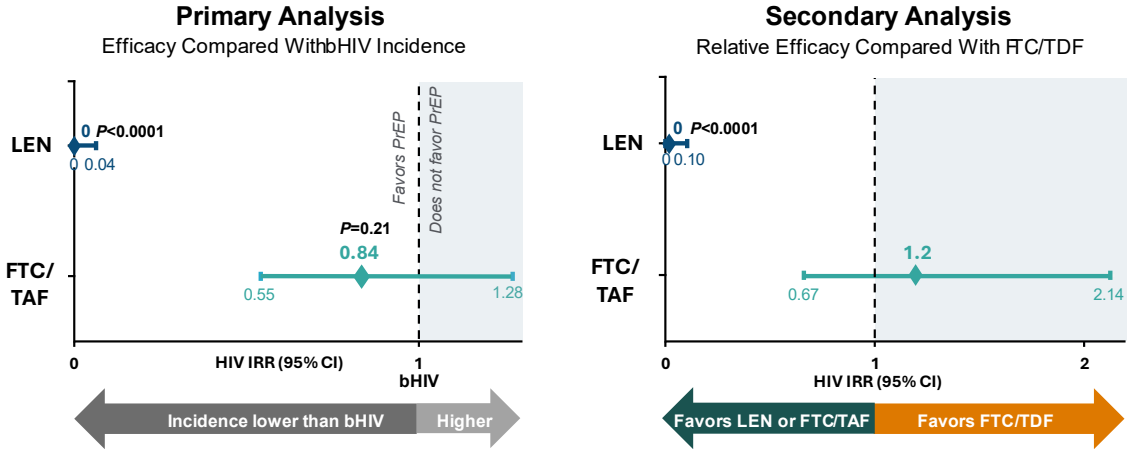


Figure 3. PURPOSE 1: Primary and Secondary Analyses[1,2]



End-of-RBP efficacy analysis[3]

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 oral 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.

Through the end of the RBP, there were 79 incident HIV cases, comprised of 52 cases in the FTC/TAF group (2630 PY; incidence rate, 1.98; 95% CI: 1.48–2.59), 25 in the FTC/TDF group (1291 PY; incidence rate, 1.94; 95% CI: 1.25–2.86), and 2 in the LEN group (2953 PY; incidence rate, 0.07; 95% CI: 0.01–0.25). Of the 2 LEN participants, 1 had good adherence to LEN and was diagnosed clinically with HIV-1 at Week 65 by typical serologic testing; retrospective RNA test was found to be positive at Week 52. The LEN concentration was above the IQ4 (15.5 ng/mL) at all assessed timepoints and was 44.6 ng/mL at HIV-1 Week 52 diagnosis. The other LEN participant missed her LEN injection at Week 52, switched to open-label FTC/TDF at Week 82 (at which time she tested negative for HIV-1), and was diagnosed with HIV-1 approximately 16 months after the last LEN injection at Week 95; the LEN concentration was above the IQ4 at all time points, with the exception of a transient dip below IQ4 at the time of her last Week 26 LEN injection and after her Week 52 missed injection. The LEN concentration was 0.65 ng/mL at HIV-1 diagnosis.

Adherence results at primary analysis[1]

Adherence to LEN was defined as on-time injections (within 28 weeks after the last injection). Most participants received their injections (LEN and placebo LEN) on time at Weeks 26 (91.5%; 4545/4967) and 52 (92.8%; 2025/2181), and adherence to injections was similar across the groups.

Adherence to FTC/TAF and FTC/TDF was evaluated at study visits using DBS analysis of TDF levels in 10% of participants, who were randomly preselected from each group. Adherence in the 10% sample of participants in the FTC/TAF and FTC/TDF groups was low and decreased over time. At Week 8, in the FTC/TAF and FTC/TDF groups, adherence was low (<2 doses/week) in 34% and 50% of participants, respectively; at Week 52, adherence was low in 84% and 93%. Among participants who acquired HIV and had data available, 34/37 participants in the FTC/TAF group and 13/14 participants in the FTC/TDF group had low or undetectable levels of TDF. In a matched case-control analysis to assess the association between adherence and efficacy in the FTC/TAF group, participants with medium (2 or 3 doses/week) or high (≥4 doses/week) adherence had lower odds of acquiring HIV than those with low adherence (odds ratio, 0.11; 95% CI: 0.01–0.49).

Persistence results at primary analysis[5]

Persistence to LEN was defined as on-time injections (within 28 weeks after the last injection) at Week 26 and Week 52. Persistence was evaluated in 10% of participants, who were randomly preselected from each group and limited to those who had ≥1 year of study follow-up at time of interim analysis. Most participants demonstrated high persistence to LEN and placebo LEN, with 79.5% on LEN (n=112), 81.8% on FTC/TAF with placebo LEN (n=99), and 75.9% on FTC/TDF with placebo LEN (n=54) with on-time injections at Week 26 and Week 52.

Persistence to daily oral FTC/TAF or FTC/TDF was assessed by TFV-DP concentration in DBS at Weeks 13, 26, 39, and 52. Compared with LEN injections, persistence to daily oral FTC/TAF or FTC/TDF was significantly lower, with 5.2% of participants (n=153) having DBS TFV-DP concentrations consistent with ≥4 doses/week through Week 52 (P<0.0001).

Safety

Primary analysis safety results

LEN, FTC/TAF, and FTC/TDF were generally well tolerated, with fewer gastrointestinal AEs in the LEN group than in either the FTC/TAF or FTC/TDF groups (Table 2). LEN ISRs were relatively common, and most were Grade 1 or 2. Six deaths occurred, all in the FTC/TAF group; none of these were considered by the investigator to be related to study drug.[1]

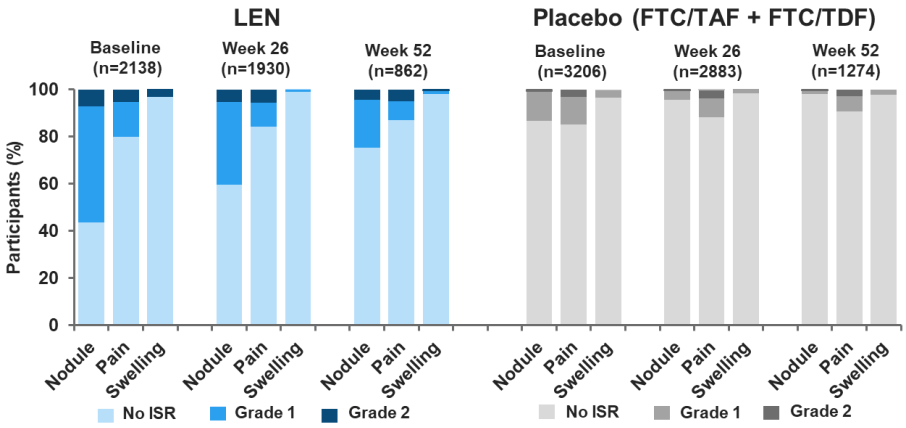
The most common AEs were ISRs. A total of 25,329 injections were administered, with 10,154 administered to 2138 participants in the LEN group and 15,175 administered to 3206 participants receiving placebo injection in the FTC/TAF and FTC/TDF groups. The most common ISRs were SUBQ nodules, injection site pain, and swelling, which occurred in 63.8%, 31.2%, and 4.4% of LEN participants, respectively, and in 16.6%, 23.7%, and 5.4% of participants who received placebo injections.[6] No Grade 4 ISRs occurred, and the frequency of ISRs decreased over time (Figure 4). Four ISRs (0.2%) that led to premature discontinuation occurred in the LEN group; all were reported as SUBQ nodules, including 1 that was also reported as injection site pain. No participants who receive a placebo injection discontinued due to ISR. No keloid scars were reported in any group.[1]

Table 2. PURPOSE 1: Safety Summary[1]

AE, n (%)		Primary Analysis		
		LEN (n=2138)	FTC/TAF (n=2137)	FTC/TDF (n=1070)
Any AE (excluding ISRs)		1631 (76.3)	1665 (77.9)	830 (77.6)
Grade ≥3 AE		88 (4.1)	95 (4.4)	50 (4.7)
SAE		59 (2.8)	85 (4)	35 (3.3)
AEs that led to discontinuation of study drug[a]		5 (0.2)	2 (<0.1)	0
Common AEs in ≥5% of participants in any group (excluding ISRs)	UTI	307 (14.4)	305 (14.3)	163 (15.2)
	Genitourinary tract chlamydia infection	300 (14)	317 (14.8)	129 (12.1)
	Headache	285 (13.3)	352 (16.5)	155 (14.5)
	URTI	271 (12.7)	274 (12.8)	121 (11.3)
	Vaginal discharge	166 (7.8)	191 (8.9)	87 (8.1)
	Vulvovaginal candidiasis	146 (6.8)	172 (8)	67 (6.3)
	Nausea	144 (6.7)	234 (10.9)	142 (13.3)
	Genitourinary tract gonococcal infection	141 (6.6)	157 (7.3)	66 (6.2)
	Diarrhea	133 (6.2)	161 (7.5)	67 (6.3)
	Vomiting	125 (5.8)	235 (11)	107 (10)
	Dizziness	120 (5.6)	141 (6.6)	79 (7.4)
Laboratory abnormalities[b]	Any	1929 (90.7)	1904 (90.1)	959 (91)
	Grade 3	92 (4.3)	81 (3.8)	50 (4.7)
	Grade 4	20 (0.9)	22 (1)	11 (1)
ISRs[c]	Any related to LEN, placebo LEN, or trial procedures	1470 (68.8)	755 (35.3)	363 (33.9)
	Led to discontinuation of study drug	4 (0.2)	0	0
	Grade 3[d]	4 (0.2)	2 (<0.1)	2 (0.2)

[a]AEs that led to discontinuation of LEN were nausea (n=1), decreased CrCl (n=1), increased liver enzyme levels (n=1), spontaneous abortion (n=1), and suicide attempt with major depression (n=1). In the FTC/TAF group, AEs that led to discontinuation were suicide attempt, depressive symptoms, and drug overdose (n=1, all in the same participant) and angioedema (n=1).
[b]Percentages shown are based on the number of participants who had ≥1 postbaseline laboratory result (LEN, n=2126; FTC/TAF, n=2113; FTC/TDF, n=1054).
[c]Reactions to trial-related injections only; percentages shown are based on the number of participants who received ≥1 placebo or LEN injection (LEN, n=2138; FTC/TAF, n=2136; FTC/TDF, n=1070).
[d]Grade 3 ISRs consisted of injection site ulcer (LEN, n=3; FTC/TAF, n=2; FTC/TDF, n=1), nodule (LEN, n=1), and pain (FTC/TDF, n=1).
Note: All AEs were coded according to MedDRA v27.0.

Figure 4. PURPOSE 1: Frequency of Common Grade ≤2 ISRs Over Time[7]



Pregnancy outcomes at primary analysis

Pregnancies occurred in 487 participants, with a total of 509 pregnancies (LEN, n=193; FTC/TAF, n=218; FTC/TDF, n=98). Five participants acquired HIV-1 during pregnancy (FTC/TAF, n=4; FTC/TDF, n=1); none of these cases occurred in the LEN group, and there were no cases of vertical transmission in any group. Pregnancy outcomes were balanced across arms (Table 3). Overall, there were 10 congenital abnormalities (LEN, n=6; FTC/TAF, n=4)[8], which was within the expected background incidence rate.[9,10] The congenital abnormalities in the LEN group were congenital hemangioma, umbilical hernia, left hand polydactyly, perimembranous ventricular septal defect, congenital ventricular septal defect, and congenital reducible umbilical hernia (each, n=1). Among all participants who received ≥1 LEN injection during pregnancy or postpartum, 33.3% (44/132) reported ISRs; all ISRs were Grade 1 or 2 in severity. The most common ISRs were nodules (26.5%; n=35) and injection site pain (12.9%; n=17). One AE (0.5%) of spontaneous miscarriage led to LEN discontinuation.[8]

Table 3. PURPOSE 1: Pregnancy Outcomes[8]

Pregnancy Outcomes, n (%)		Primary Analysis		
		LEN (n=193)	FTC/TAF (n=218)	FTC/TDF (n=98)
Pregnancy status	Completed	186 (96.4)	207 (95)	97 (99)
	Unknown	7 (3.6)	11 (5)	1 (1)
Live births[a]		128 (66.3)	119 (54.6)	56 (57.1)
Pregnancy losses		60 (31.1)	89 (40.8)	41 (41.8)
Stillbirths[b]		5 (2.6)	6 (2.8)	3 (3.1)
Induced abortions		35 (18.1)	50 (22.9)	23 (23.5)
Spontaneous miscarriages[c]		20 (10.4)	33 (15.1)	15 (15.3)

[a]Data included 3 pregnancies that had 2 outcomes due to twins.
[b]Defined as fetal death that occurred at ≥20 weeks' gestation.
[c]Defined as fetal death that occurred at <20 weeks' gestation.

End-of-RBP safety results[3]

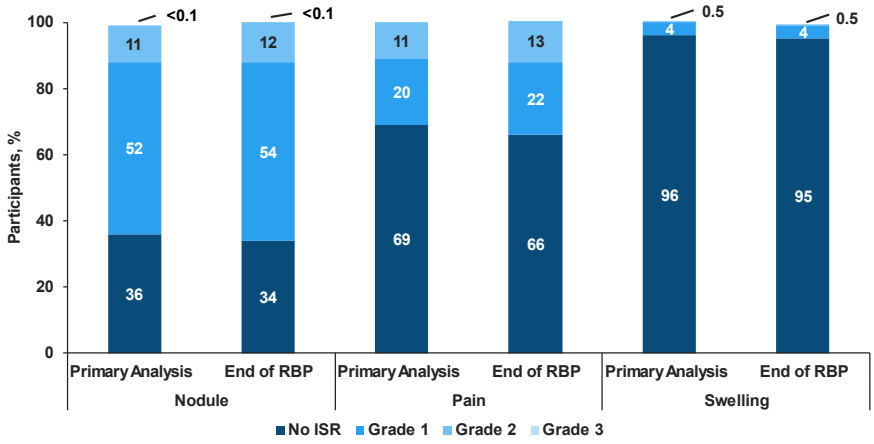
Through the end of the RBP, no new safety concerns with LEN were noted, and no new discontinuations due to ISRs occurred (Table 4). The incidence and severity of ISRs were generally similar to those reported in the primary analysis (Figure 5).

Table 4. PURPOSE 1 End-of-RBP Analysis: Safety Outcomes[3]

Safety Outcomes, n (%)		End-of-RBP Analysis LEN (n=2140)
Any-grade AE (excluding ISRs)		1743 (81)
Grade ≥3 AE		114 (5)
SAEs		81 (4)
AEs that led to study drug discontinuation		9 (<1)
AEs that occurred in ≥10% of participants (excluding ISRs)	Genitourinary chlamydia infection	352 (16)
	URTI	344 (16)
	UTI	344 (16)
	Headache	327 (15)
ISRs		1519 (71)
Grade 2		444 (21)
Grade 3 (highest grade reported)		4 (<1)
Led to discontinuation of study regimen		4 (<1)

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

Figure 5. PURPOSE 1 Primary and End-of-RBP Analyses: ISRs in LEN Participants[3]



References

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Abbreviations

AE=adverse event
bHIV=background HIV
DBS=dried blood spot
FTC=emtricitabine
IQ4=inhibitory quotient 4
IRR=incidence rate ratio
ISR=injection site reaction
LEN=lenacapavir
MedDRA=Medical Dictionary for Regulatory Activities
OLE=open-label extension
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
URTI=upper respiratory tract infection
UTI=urinary tract infection

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Yeztugo, Descovy, and Truvada US Prescribing Information available at:
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www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi;
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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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