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Yeztugo® (lenacapavir) Seroconversion

This document is in response to your request for information regarding the use of Yeztugo® (lenacapavir [LEN]) for HIV-1 pre-exposure prophylaxis (PrEP) and cases of seroconversion. This response was developed according to principles of evidence-based medicine and includes data from phase 3 clinical trials.

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Summary

Product Labeling[1]

There were 2 incident infections (infections that occurred after starting LEN for HIV-1 PrEP) and 4 prevalent infections (acute infection at baseline identified after starting LEN for HIV-1 PrEP) among participants in the LEN arm of the PURPOSE 1 trial. Both incident infections occurred after the time of the primary analysis. One of the incident infections occurred in a participant after LEN exposures fell below the target concentration following discontinuation of LEN, and virus from this participant had no LEN resistance-associated capsid substitutions detected. The second participant with an incident infection had viral loads that were too low for genotyping. Viruses with LEN resistance-associated capsid substitutions were detected in 3 of the 4 participants with prevalent infections, 2 with N74D and 1 with T107A.

There were 3 incident and 4 prevalent infections among participants in the LEN arm of the PURPOSE 2 trial. One of the incident infections occurred after the time of the primary analysis. LEN resistance-associated substitutions were detected in viruses from the 3 participants with incident infections, 2 with N74D, and 1 with Q67H/K70R. Gentoypic data were available for 3 of the 4 participants with prevalent infections. Viruses with LEN resistance-associated capsid substitutions were detected in 2 of these 3 participants, both with N74D.

Clinical Data on Seroconversions During LEN Use for HIV-1 PrEP

In the ongoing phase 3 PURPOSE 1 study in CGW (N=5345), seroconversions were assessed at multiple analyses[2-4]:

- At the primary analysis, none of the 2138 participants in the LEN group acquired HIV-1.[2]

- Through the end of the RBP, there were 2 cases of seroconversion in the LEN group. One participant had good adherence to LEN and was diagnosed clinically with HIV-1 at Week 65 by typical serologic testing; a retrospective RNA test was found to be positive at Week 52. 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.[3]
- Through OLE Week 52, there were no new incident HIV acquisitions in either the continuous LEN group or in the LEN switch group.[4]

In the ongoing phase 3 PURPOSE 2 study in CGM, TGW, TGM, and GNB individuals, seroconversions were assessed at multiple analyses[5-8]:

- At the primary analysis, 2 of the 2179 participants in the LEN group acquired HIV. Retrospective standard HIV-1 RNA viral load testing of samples obtained at previous visits did not reveal evidence of delay of HIV seroconversion or delayed diagnosis with standard HIV-1 testing. Both participants had the N74D capsid resistance mutation. Neither participant reported symptoms of HIV seroconversion.[5]
- Through the end of the RBP, 1 additional participant in the LEN group acquired HIV at Week 52 (according to standard HIV testing) and was found to have Q67H and K70R resistance mutations.[6,7]
- Through OLE Week 52, there was 1 new case of incident HIV in the continuous LEN group at OLE Week 39; this participant received all injections on time, had LEN concentrations above the IQ4 at most assessments, and had the capsid mutation Q67H at HIV diagnosis.[8]

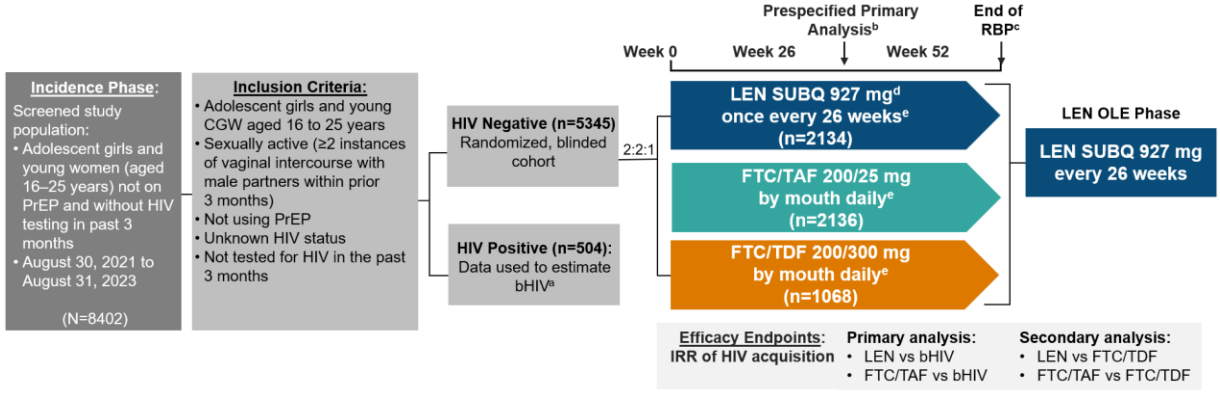
Clinical Data on Seroconversions During LEN Use for HIV-1 PrEP

PURPOSE 1: LEN in CGW

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 CGW 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 CGW 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.[2]

Figure 1. PURPOSE 1: Study Design[2,3,7]



[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]The prespecified primary analysis was when 50% of participants had completed ≥52 weeks of follow-up.
[c]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.
[d]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.
[e]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.

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 was 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.[2]

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.[2]

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

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)

Seroconversions

At the primary endpoint analysis, there were no cases of seroconversion in the LEN group (1939 PY; incidence rate, 0 per 100 PY; 95% CI: 0–0.19), compared with 39 cases in the FTC/TAF group (1932 PY; incidence rate, 2.02 per 100 PY; 95% CI: 1.44–2.76) and 16 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.[2]

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 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). Of the 2 participants in the LEN group, 1 had good adherence to LEN and was diagnosed clinically with HIV-1 at Week 65 by typical serologic testing; a 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 time points 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.[3]

Through OLE Week 52, there were no new incident HIV acquisitions in either the continuous LEN group (n=2136; incidence per 100 PY, 0.04; 95% CI: 0.01–0.015; 4682 PY of follow-up) or the LEN switch group (n=2496; incidence per 100 PY, 0; 95% CI: 0–0.13; 2779 PY of follow-up). The combined HIV incidence (95% CI) among participants who received LEN in the RBP plus those in the LEN switch group was 0.03 (0–0.1) per 100 PY.[4]

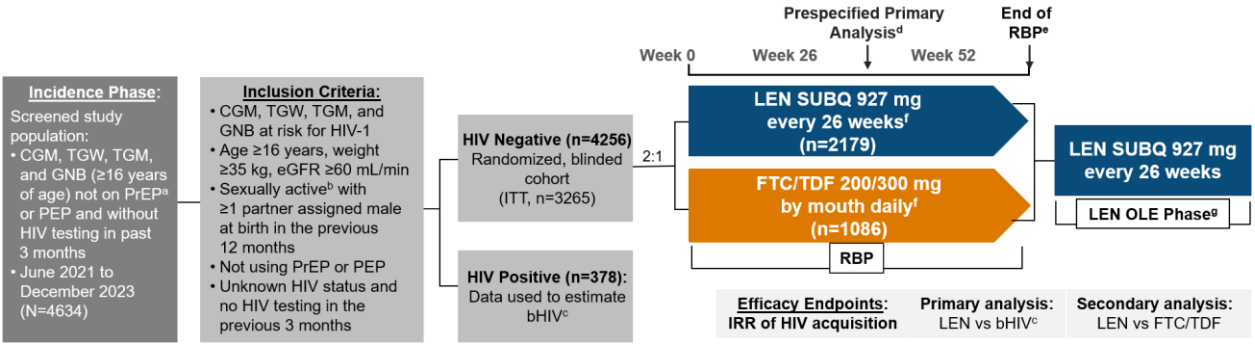
PURPOSE 2: LEN in CGM, TGW, TGM, and GNB Individuals

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 2). 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.[5]

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.[5]

Figure 2. PURPOSE 2: Study Design[5,6,9]



Abbreviation: PEP=post-exposure prophylaxis.

[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 the 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 2).[5]

Table 2. PURPOSE 2: Select Baseline Demographics and Disease Characteristics[5]

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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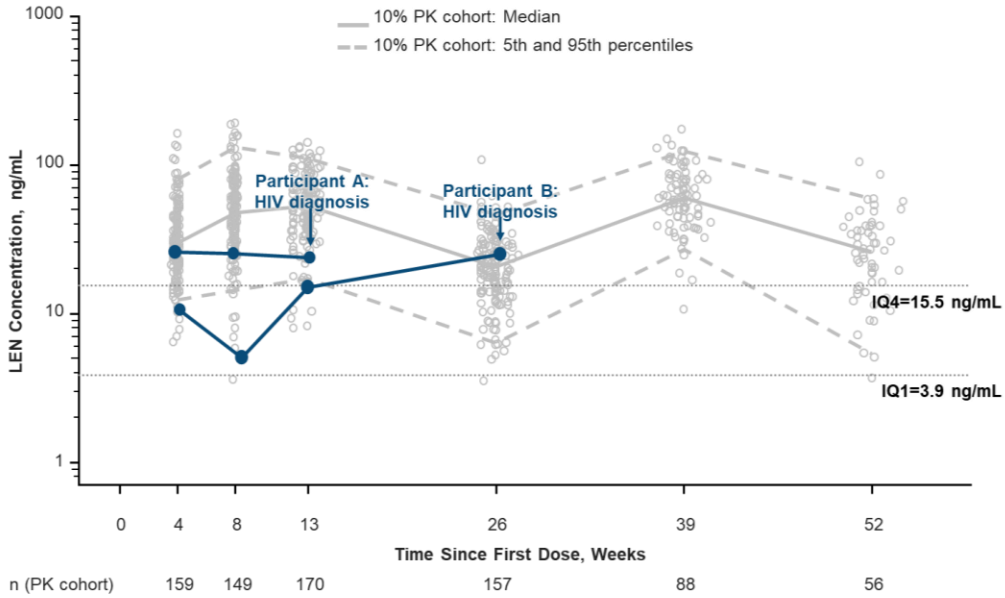
Key Demographics and Characteristics		LEN (n=2183)	FTC/TDF (n=1088)
Gender identity, n (%)	CGM	1697 (77.7)	846 (77.8)
	TGW	315 (14.4)	161 (14.8)
	GNB[d]	136 (6.2)	63 (5.8)
	TGM	29 (1.3)	14 (1.3)
	Other[e]	6 (0.3)	4 (0.4)
Sexually transmitted infections,[f] n (%)	*Chlamydia trachomatis*	253 (11.6)	126 (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.

Seroconversions

The 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). In the LEN group, there were 2 incident HIV cases (0.1 per 100 PY; 95% CI: 0.01–0.37), one each at 13 and 26 weeks after the first dose (Figure 3). 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 dried blood stains) or had documented discontinuation of FTC/TDF >10 days prior to diagnosis, and 1 participant was found to have an M184V resistance mutation.[5]

Figure 3. PURPOSE 2: LEN Plasma Concentrations of the PK Cohort[a] and the Two Participants Who Acquired HIV-1[5]



[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 was 4 times the protein-adjusted 95% effective concentration in vitro.

Table 3. PURPOSE 2: Test Results of the Two LEN Participants Who Acquired HIV-1[10]

Participant A	Week 0	Week 4	Week 8	HIV Diagnosis at Week 13
Rapid Ag/Ab[a]	(-)	(-)	(-)	(+)
Central Ag/Ab[b]	(-)	(-)	(-)	(+)
HIV-1-/2 Ab diff[c]				(HIV-1+ / HIV-2-)[d]
Qualitative RNA				(+)
VL,[e] c/mL	ND	ND[f]	ND[f]	934,000
SCA,[g] c/mL	ND[f]		ND[f]	4.8[f]

Participant B	Week 0	Week 4	Week 8	Week 13	HIV Diagnosis at Week 26
Rapid Ag/Ab[a]	(-)	(-)	(-)	(-)	(-)
Central Ag/Ab[b]	(-)	(-)	(-)	(-)	(+)
HIV-1/-2 Ab diff[c]					(HIV-1+ / HIV-2-)[d]
Qualitative RNA					(+)
VL,[e] c/mL	ND			ND[f]	14,100
SCA,[g] c/mL	ND[f]	ND[f]	ND[f]	ND[f]	

Abbreviations: diff=differentiation; ND=not detected; SCA=single-copy assay; VL=viral load.
[a]Local rapid HIV-1/-2 Ag/Ab test.
[b]Central laboratory fourth-generation Ag/Ab test.
[c]HIV-1/-2 Ab differentiation assay.
[d]Ab differentiation intermediate for HIV-1, negative for HIV-2. HIV-1 confirmed by qualitative RNA and quantitative RNA.
[e]HIV-1 RNA quantitative viral load; blank denotes test not done.
[f]Tests run from archived samples after HIV diagnosis. ND denotes no HIV-1 RNA detected.
[g]HIV-1 RNA single-copy assay.

Through the end of the RBP, there were a total of 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.[6]

The additional participant in the LEN group who acquired HIV-1 through the end of the RBP had Q67H and K70R resistance mutations.[7] This participant 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 GNB 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 in >95th percentile of the subset of participants in the PK analysis).[6]

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.[8]

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10. Kelley CF, Acevedo-Quinones M, Agwu AL, et al. Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons [Supplementary Appendix]. *N Engl J Med.* 2024.

Abbreviations

Ab=antibody
Ag=antigen
bHIV=background HIV incidence
c/mL=copies per mL
CGM=cisgender men
CGW=cisgender women
FTC=emtricitabine
GNB=gender nonbinary
IQ1/4=inhibitory quotient 1/4
IRR=incidence rate ratio
LEN=lenacapavir
mITT=modified ITT
OLE=open-label extension
PK=pharmacokinetic(s)
PrEP=pre-exposure prophylaxis
PY=person years
RBP=randomized blinded phase
SUBQ=subcutaneous
TAF=tenofovir alafenamide
TDF=tenofovir disoproxil fumarate
TFV-DP=tenofovir diphosphate
TGM=transgender men
TGW=transgender women

Product Label

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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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