GILEAD | Medical Information

Sunlenca® (lenacapavir) Use in Heavily Treatment-Experienced Individuals

This document is in response to your request for information regarding the use of Sunlenca® (lenacapavir [LEN]) in people with HIV-1 (PWH) who are heavily treatment-experienced (HTE), including those with baseline (BL) resistance.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_pi.

Summary

Product Labeling[1]

LEN, in combination with other ARV(s), is indicated for the treatment of HIV-1 infection in HTE adults with multidrug resistant HIV-1 whose current ARV regimen is failing due to resistance, intolerance, or safety considerations.

Clinical Studies on LEN Use in HTE Individuals

In the ongoing phase 2/3 CAPELLA study that is evaluating LEN as an add-on therapy to a failing regimen in HTE PWH with multidrug resistance, significantly more participants in the LEN group than in the PBO group met the primary endpoint of a ≥0.5-$\log_{10}$ reduction in HIV-1 RNA at the end of the 14-day functional monotherapy phase (88% vs 17%, respectively; $P<0.001$).[2]

- At Week 156, 61.4% of participants achieved virologic suppression per FDA Snapshot, and 84.6% achieved virologic suppression per M=E analysis.[3]
- Through Week 156, 14 participants developed LEN resistance. There were no new cases of LEN resistance between Weeks 104 and 156.[3]
- At a median (IQR) follow-up of 165 (146–178) weeks, Grade 3 TRAEs were reported in 6 participants (8.3%), and 2 participants discontinued study drug treatment due to Grade 1 injection site nodules.[3]
- Subgroup analyses at Week 52 showed that LEN + OBR was associated with high rates of virologic suppression across various demographics and BL characteristics.[4]
- Through Week 52, the mean change from BL in SF-36, EQ-5D-5L, and NPRS scores did not reach the MIC thresholds, and most symptoms were reported as bothersome by fewer participants at Week 52 than at BL.[5]

Real-World Data on LEN Use in HTE Individuals

Real-world data on LEN use in HTE PWH are summarized in Table 7 below. Data may not be all inclusive.[6-11]

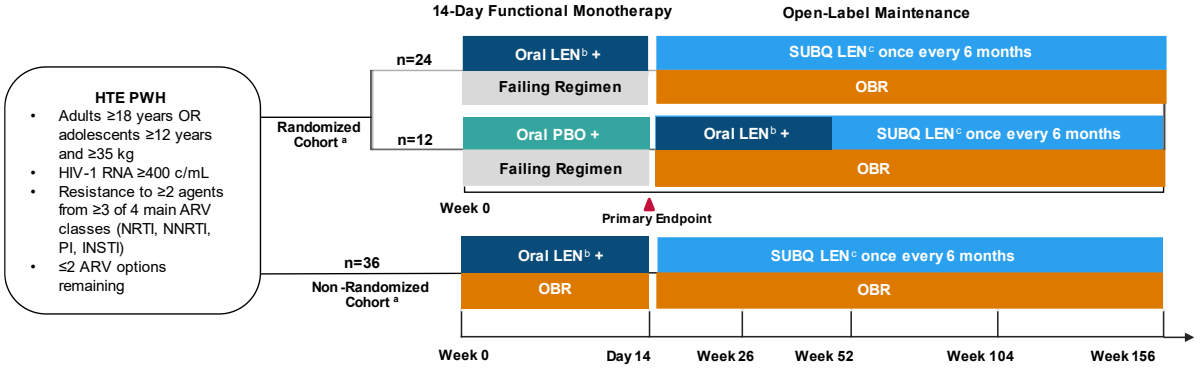
Clinical Studies on LEN Use in HTE Individuals

CAPELLA: LEN in HTE PWH

Study design and demographics

CAPELLA (NCT04150068) is an ongoing, phase 2/3, double-blind, PBO-controlled clinical study designed to evaluate LEN as add-on therapy to a failing regimen in HTE PWH with multidrug resistance. According to the change in the HIV-1 RNA level between the screening and cohort selection visits, participants were enrolled in either the randomized or non-randomized cohorts. Participants in the randomized cohort were assigned to receive oral LEN or PBO in a 2:1 ratio for 14 days, in addition to continuing their failing regimen. The non-randomized cohort started LEN (2-week oral initiation then SUBQ) with an OBR (Figure 1; Table 1). Both cohorts progressed to the maintenance phase, which is evaluating the safety and efficacy of SUBQ LEN administered every 6 months in combination with an OBR.[3]

Figure 1. CAPELLA: Study Design[3,12]



Abbreviations: ATV/r=atazanavir/ritonavir; COBI=cobicistat; EFV=efavirenz; ETV=etravirine; NVP=nevirapine; TPV=tipranavir.
[a]Participants with a <0.5 log_{10} decline in HIV-1 RNA and HIV-1 RNA ≥400 c/mL were enrolled in the randomized cohort; participants were enrolled in the non-randomized cohort if they had a ≥0.5 log_{10} decline in HIV-1 RNA and/or had HIV-1 RNA <400 c/mL or were enrolled after the randomized cohort was fully recruited.
[b]Oral LEN dosing schedule: Day 1, 600 mg; Day 2, 600 mg; and Day 8, 300 mg.
[c]SUBQ LEN dosing schedule: 927 mg (2 × 1.5 mL) on Day 15 and then every 6 months.
Note: ATV, ATV/COBI, ATV/r, EFV, ETV, NVP, and TPV were not permitted for use in OBR.

The primary endpoint was the proportion of participants who achieved a ≥0.5-log_{10} c/mL reduction in HIV-1 RNA from BL to the end of the functional monotherapy phase in the randomized cohort (ie, Day 15). Secondary endpoints included the percentage of participants in the randomized cohort with HIV-1 RNA <50 c/mL or <200 c/mL and the change in CD4 cell count at Weeks 26, 52, 104, and 156.[3]

Table 1. CAPELLA Study: BL Demographics and Disease Characteristics[3,13]

Key Demographics and Characteristics[a]	Randomized Cohort		Non-Randomized Cohort	Total (N=72)
	LEN (n=24)	PBO (n=12)	LEN (n=36)	
Age, median (IQR), years	55 (50–61)	54 (49–55)	49 (38–60)	52 (45–59)
Male sex at birth, n (%)	17 (71)	9 (75)	28 (78)	54 (75)

Key Demographics and Characteristics[a]		Randomized Cohort		Non-Randomized Cohort	Total (N=72)
		LEN (n=24)	PBO (n=12)	LEN (n=36)	
Race,[b] n (%)	White	12 (50)	4 (36)	13 (36)	29 (41)
	Black	10 (42)	6 (55)	11 (31)	27 (38)
	Asian	2 (8)	1 (9)	12 (33)	15 (21)
Hispanic or Latinx ethnicity,[b] n (%)		6 (25)	4 (36)	5 (14)	15 (21)
HIV-1 RNA[c]	Median (IQR), log_{10} c/mL	4.2 (3.2–4.6)	4.9 (4.5–5.3)	4.5 (3.3–4.9)	4.5 (3.5–4.9)
	>100,000 c/mL, n (%)	1 (4)	6 (50)	7 (19)	14 (19)
CD4 count	Median (IQR), cells/mcL	172 (99–248)	85 (39–109)	195 (56–392)	150 (76–286)
	<50 cells/mcL, n (%)	3 (13)	4 (33)	9 (25)	16 (22)
	≥50 to <200 cells/mcL, n (%)	13 (54)	7 (58)	10 (28)	30 (42)
Known resistance to ≥2 drugs in class, n (%)	NRTI	23 (96)	12 (100)	36 (100)	71 (99)
	NNRTI	22 (92)	12 (100)	36 (100)	70 (97)
	PI	20 (83)	8 (67)	30 (83)	58 (81)
	INSTI	20 (83)	7 (58)	23 (64)	50 (69)
	All four major classes	14 (58)	3 (25)	16 (44)	33 (46)
Resistance to entry inhibitors, n/N (%)	MVC	19/24 (79)	8/11 (73)	14/26 (54)	41/61 (67)
	IBA	8/23 (35)	3/10 (30)	6/25 (24)	17/58 (29)
	FTR	5/23 (22)	5/10 (50)	7/21 (33)	17/54 (31)
	T20	2/23 (9)	3/10 (30)	0/25 (0)	5/58 (9)

[a]Percentages may not equal 100 due to rounding.
[b]Collection of race or ethnicity data was prohibited by local regulators for 1 participant in the PBO group and was excluded from the denominator of the percentage calculation.
[c]Two participants in the non-randomized cohort had HIV-1 RNA >400 c/mL at screening but <50 c/mL at enrollment.

Twenty-two percent of all participants (16/72) did not have changes in their OBR before they entered the open-label maintenance phase; the ARV classes and agents that comprised the failing regimen and OBR are shown in Table 2.[14]

Table 2. CAPELLA Study: Composition of Failing Regimens and OBR[15]

		Failing Regimen (N=72)	OBR (N=72)
Drug class/agent, %	NRTI	82	85
	INSTI	68	65
	PI	63	63
	NNRTI	31	33
	IBA	19	24
	MVC	14	14
	FTR	6	11
	T20	6	7
Number of fully active ARV agents, 0/1/≥2, %		42/36/22	17/38/46
OSS,[a] median		1	2

[a]OSSs were calculated with a proprietary algorithm (Monogram Biosciences Inc.), and investigators provided data for scoring from historical resistance reports. An OSS of 1 indicated full susceptibility; 0.5 indicated partial susceptibility; and 0 indicated no susceptibility. The OSS of the OBR was the sum of the individual scores.

BL resistance analyses[16]

The study enrolled participants who had resistance to ≥2 ARVs in ≥3 of the four main ARV classes (NRTIs, NNRTIs, PIs, and INSTIs; Table 3 and Table 4). BL resistance in these participants was assessed using genotypic and phenotypic assays (Monogram Biosciences, Inc.) at screening or historical data provided by the investigators. BL HIV-1 capsid genotypic

and phenotypic analyses were also performed. At BL, no RAMs associated with LEN resistance (eg, L56I, M66I, Q67H, K70N, K74D/S, and T107N) were found in the 62 participants for whom these data were available.

Table 3. CAPELLA Study: RAMs per ARV Class at BL[16]

	NRTI	NNRTI	PI	INSTI
Participants with RAMs, %	99	94	83	67
RAMs per ARV class, mean number per participant	3.8	2.4	4.1	1.3

Table 4. CAPELLA Study: BL Resistance to NRTI, NNRTI, PI, and INSTI Classes by Cohort and in the Overall Population[16,17]

Resistance[a] to ARV Class (Yes/No)				Participants, n (%)		
NRTI[b]	NNRTI	PI	INSTI	Randomized Cohort (n=36)	Non-Randomized Cohort (n=36)	Overall (N=72)
✓	✓	✓	✓	17 (47)	16 (44)	33 (46)
✓	✓	✓	–	9 (25)	13 (36)	22 (31)
✓	✓	–	✓	8 (22)	5 (14)	13 (18)
✓	–	✓	✓	2 (6)	0	2 (3)
–	✓	✓	✓	0	1 (3)	1 (1)
–	✓	–	✓	0	1 (3)[c]	1 (1)

[a]Resistance to ≥2 ARVs in the class. To be eligible for the study, participants had to have resistance to ≥2 ARVs from ≥3 of the four classes noted above.
[b]For this study, M184V/I alone was not sufficient to fulfill the NRTI resistance criteria.
[c]This participant had three-class resistance in the presence of NRTI mutation M184V/I only, which was not sufficient to fulfill the NRTI resistance criteria in this study.

Efficacy results

Day 15: randomized cohort results[2]

From BL to Day 15 in this study, LEN showed potent antiviral activity when added to a failing regimen. Significantly more participants in the LEN group than in the PBO group met the primary endpoint of a ≥0.5-$\log_{10}$ reduction in HIV-1 RNA at the end of the 14-day functional monotherapy phase (88% [21/24] vs 17% [2/12], respectively; $P<0.001$) and had a greater mean change in HIV-1 RNA (-2.1 vs 0.07 $\log_{10}$ c/mL, respectively; $P<0.001$).

Week 26: subgroup analysis by BL HIV entry inhibitor resistance[18]

At Week 26 in both cohorts, treatment response to LEN + OBR was unaffected by BL entry inhibitor susceptibility, as no significant difference in susceptibility was observed between participants with viral suppression (HIV-1 RNA <50 c/mL) and those with treatment failure (HIV-1 RNA ≥50 c/mL or no virologic data; $P>0.1$).

Week 52: subgroup analysis by BL characteristics[4]

Among all participants (n=72), HIV-1 RNA <50 c/mL was achieved at a rate of 78%. Several prespecified, post hoc subgroup analyses of all participants (n=72) were conducted to determine the efficacy of LEN at Week 52 according to selected BL demographics (ie, age, sex at birth, and race) as well as BL CD4 and HIV-1 RNA values, BL number of fully active agents in OBR and BL resistance to INSTI, and BL use of ARV agents (eg, DTG, DRV, IBA, or FTR). There were no statistically significant differences between the subgroups.

Week 104 results[19,20]

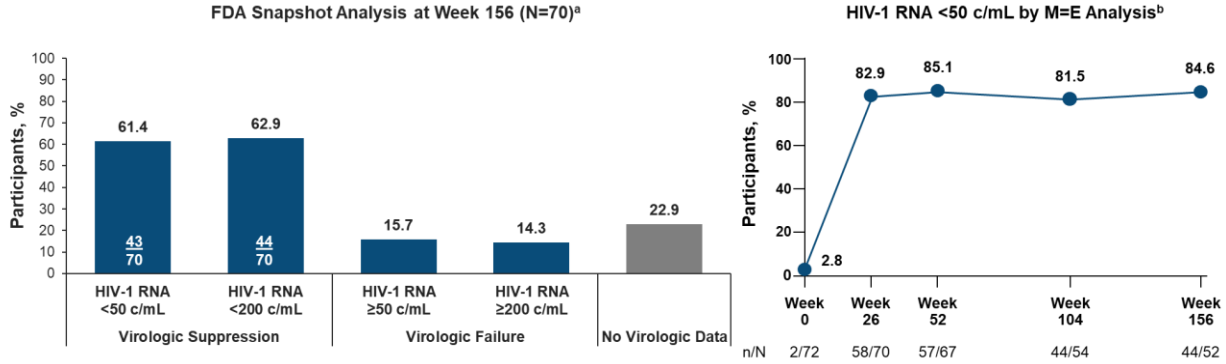
Twelve participants (17%) had no fully active ARVs in their OBR, with an OSS of 2 in the cohort randomized to LEN, 1.5 in the PBO cohort, and 2 in the non-randomized LEN cohort. In an overall missing=failure analysis at Week 104, 44/71 participants (62%) had HIV-1 RNA <50 c/mL, and 45/71 (63%) had HIV-1 RNA <200 c/mL. At Week 104, 10 participants had HIV-1 RNA >50 c/mL while on study drug; 6 of these participants had achieved virologic suppression at ≥1 prior visit. The mean increase in CD4 cell count from BL to Week 104 in the 55 participants with available data was 122 cells/mcL.

Fourteen participants developed LEN resistance through Week 104, consisting of the following LEN RAMs: Q67H/K/N (n=8), K70H/N/R/S (n=7), M66I (n=6), T107A/C/N (n=6), N74D/H/K (n=5), and A105S/T (n=5). LEN RAMs were detected in combinations of 2 to 4 substitutions in 11 participants and occurred individually in 3 participants. All participants with LEN RAMs either had inadequate plasma concentrations of drugs in the OBR (n=10) or had no fully active drugs in their OBR (n=4). Of these 14 participants, 7 resuppressed on LEN following improved adherence (n=5) or following changes to their OBR (n=2).

Week 156: maintenance phase results[3]

At Week 156, with a median (IQR) duration of follow-up on LEN of 165 (146–178) weeks, 52/72 participants (72%) had available HIV-1 RNA data. Overall, 98% of the SUBQ doses were administered within ±14 days of the scheduled time. At Week 156, 61.4% and 84.6% of participants achieved virologic suppression per FDA Snapshot and M=E analyses, respectively (Figure 2).

Figure 2. CAPELLA Study: Virologic Outcomes Through Week 156[3]

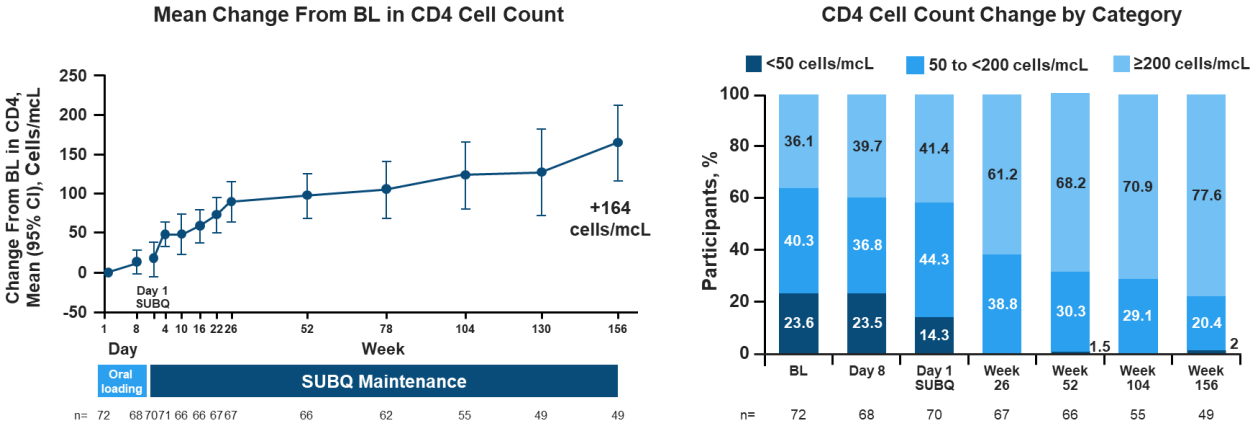


[a]Two participants who had missing HIV-1 RNA at Week 156 and had completed the study before reaching the upper limit of the analysis window for Week 156 were excluded.
[b]The denominator was the number of participants with non-missing HIV-1 RNA values at each time point.

CD4 changes through Week 156[3]

Overall, CD4 count increased by a mean (95% CI) of 164 (116–211) cells/mcL from BL to Week 156. At Week 156, the proportion of participants with CD4 counts <50 cells/mcL decreased from 24% of participants at BL to 2%, and the proportion of participants with CD4 counts <200 cells/mcL decreased from 64% to 22% (Figure 3).

Figure 3. CAPELLA Study: Changes in CD4 Counts From BL Through Week 156[3]



Note: Day 1 was the first day SUBQ LEN was administered.

Post-BL resistance analyses through Week 156[3]

Post-BL resistance analyses were conducted in participants with virologic failure, defined as HIV-1 RNA ≥50 c/mL and <1-$\log_{10}$ decrease in HIV-1 RNA 4 weeks after LEN initiation or virologic rebound (HIV-1 RNA ≥50 c/mL after a prior measurement of <50 c/mL or a >1-$\log_{10}$ increase from nadir).

Treatment-emergent resistance to LEN developed in 14 participants: between BL and Week 26, n=8; between Week 26 and 52, n=1; between Week 52 and 104, n=5 (Table 5). Although no new cases of LEN resistance were reported between Week 104 and 156, 2 participants developed additional LEN RAMs (K70R + T107N with existing Q67K and T107T/N with existing K70N + N74K). All 14 participants were at high risk of developing resistance to LEN due to inadequate OBR adherence (n=10) or lack of fully active drugs in the OBR (n=4).

Table 5. CAPELLA Study: Emergent LEN Resistance Through Week 156[3]

Outcomes, n	Pooled Cohort (N=72)
Participants who met criteria for resistance testing	28
Emergent LEN resistance	14
M66I + other RAMs	6
Q67H + K70R ± A105T ± T107N	4
K70N + N74K + T107T/N	1
N74D	1
Q67H	1
Q76K + K70H	1

Five of the 14 participants with emergent LEN resistance achieved virologic resuppression while continuing LEN treatment. Of the participants who were not virologically resuppressed after LEN resistance emerged, 4 had a >1 $\log_{10}$ reduction in HIV-1 RNA, 3 had a <1 $\log_{10}$ reduction in HIV-1 RNA, and 2 returned to BL HIV-1 RNA levels. The mean (95% CI) increase in CD4 count in participants with treatment-emergent LEN resistance from BL to Week 156 was 193 (74–313) cells/mcL.

Safety results[3]

Most TEAEs through Week 156 were mild to moderate in severity and were not deemed related to LEN treatment (Table 6). Overall, 6 participants were LTFU, and 5 discontinued due to participant decision. No serious TRAEs or Grade 4 TRAEs were reported.

Table 6. CAPELLA Study: Safety Results Through Week 156[3]

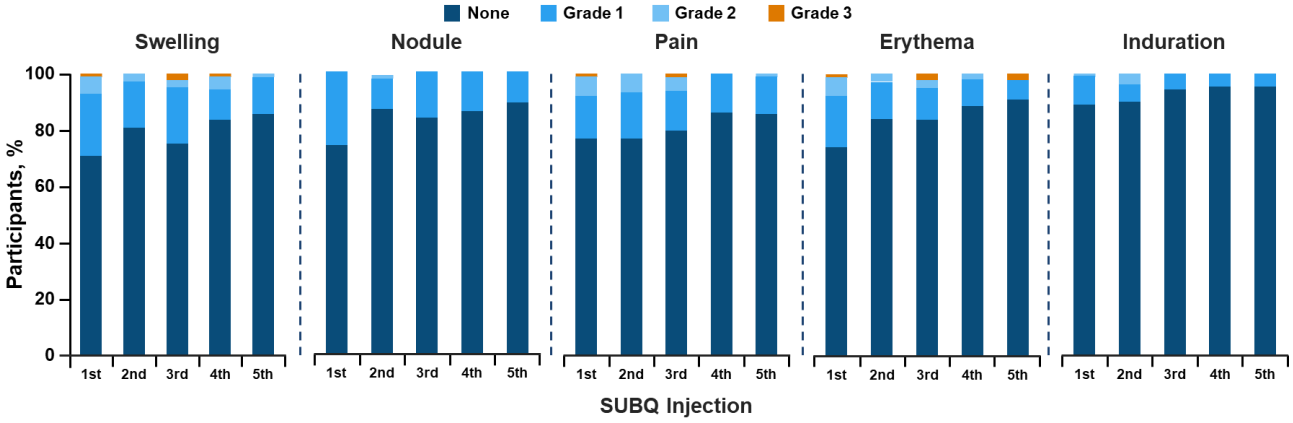
Safety Parameters, n or n (%)		Total (N=72)
Any TEAEs		71 (98.6)
Grade ≥3		31 (43.1)[a]
Serious TEAEs		22 (30.6)
Any TRAEs		57 (79.2)
Grade ≥3		6 (8.3)[b]
Serious TRAEs		0
TEAEs (excluding ISRs) that occurred in ≥15% of participants	COVID-19	18 (25)
	Diarrhea	15 (20.8)
	Nausea	14 (19.4)
	Cough	12 (16.7)
	Urinary tract infection	12 (16.7)
TEAEs that led to premature study drug discontinuation		2[c]
Deaths		3[d]

[a]Grade ≥3 TEAEs that occurred in >1 participant included pneumonia (n=4) and cellulitis, dehydration, hypotension, pneumonia staphylococcal, and squamous cell carcinoma (each, n=2).
[b]ISR (n=4); and immune reconstitution inflammatory syndrome, abdominal abscess, and rash (each, n=1).
[c]Both discontinuations occurred between Weeks 104 and 156 due to Grade 1 injection site nodules that were deemed related to LEN treatment.
[d]One participant died due to cancer on Day 90, 1 died of unknown causes on Day 551, and 1 died due to respiratory failure on Day 568. None of the deaths were deemed related to LEN treatment.

ISR results through Week 156

Most ISRs (97.2%) reported through Week 156 were Grade 1 or 2 in severity, and the frequency decreased over time (Figure 4). Overall, ISRs included injection site swelling (47.2%), injection site nodule (38.9%), injection site pain (38.9%), injection site erythema (36.1%), and injection site induration (15.3%). The median (IQR) duration of ISRs was as follows: nodules, 288 (155–548) days; induration, 190 (67–410) days; swelling, 8 (4–15) days; erythema, 5 (3–8) days; and pain, 3 (2–5) days.

Figure 4. CAPELLA Study: ISRs Related to SUBQ LEN Through Week 156[3]



PROs[5]

At Week 52, PROs were evaluated to assess change from BL in HIV symptoms (using the SF-36 [scale: 0–100; higher scores are associated with better physical health, mental health, and function] and HIV-SI scales [scale: 0–4; higher scores indicate more bothersome HIV symptoms]), overall health-related quality of life (using the EQ-5D-5L [0- to 1-point index score and a 0- to 100-point VAS score; higher numbers indicate better health and how a patient's health condition may limit or worsen the patient's daily activities]), and injection pain (using the NPRS scale [scale: 0–10; higher score indicates more intense pain]) during the most recently received injection.

At BL, the mean SF-36 physical and mental component scores were 48.5 and 48.4, respectively; normal SF-36 scores in the US are 50 for both components. Through 52 weeks, the SF-36 component summary scores remained stable (Week 52 mean change from BL: physical component, 1; mental component, -0.9), and the score changes did not reach the MIC values (2 and 3, respectively).

At Week 52, the proportion of participants who reported symptoms as bothersome decreased in 15 of 20 symptom categories, with a decrease by ≥5% for 10 of 20 symptoms. The three symptoms with the greatest decrease on the HIV-SI were fatigue or loss of energy (-15%), feeling nervous or anxious (-14%), and muscle aches or joint pain (-10%). From BL to Week 52, reports of bothersome symptoms increased by 21% for pain, numbness, or tingling in hands or feet and increased by 5% increase for headache.

At BL, the mean EQ-5D-5L index and VAS scores were 0.87 and 81, respectively; normal EQ-5D-5L index and VAS scores in adults in the US are 0.851 and 80.4, respectively. Through 52 weeks, the EQ-5D-5L scores remained stable (Week 52 mean change from BL: index, -0.06; VAS, 3), and the score changes did not reach the MIC values at any time (0.063 and 7, respectively).

The individual NPRS scores for all participants were highly variable over 52 weeks; however, the mean scores (range: 3.9–5.1) remained stable, and the mean change from BL was less than the MIC threshold of 2.

Real-World Data on LEN Use in HTE Individuals

Table 7. Real-World Data on LEN Use in HTE Individuals[6,7,9,11]

Study Design	Study Population	Efficacy and Persistence Results	Safety Results
OPERA observational, longitudinal cohort (Mounzer, 2025)[6]	116 TE PWH who received ≥1 set of LEN injections	• Of patients with BL VL <200 c/mL and ≥1 follow-up VL (n=69), the 12-month cumulative probability of maintaining VL <200 c/mL was 92% (95% CI: 80–96). Six patients (9%) had ≥1 follow-up VL ≥200 c/mL, and 67% resuppressed on LEN • Of patients with BL VL ≥200 c/mL and ≥1 follow-up VL (n=39), the 12-month cumulative probability of achieving VL <200 c/mL was 76% (95% CI: 62–88). Thirty patients (77%) had ≥1 follow-up VL <200 c/mL • Of patients with ≥2 sets of LEN injections (n=78), 91% remained on LEN at end of study	• 9% of patients with ≥2 sets of LEN injections discontinued LEN (reasons not specified) • No additional safety data were provided

Study Design	Study Population	Efficacy and Persistence Results	Safety Results

ANRS MIE French, retrospective, observational study (Charpentier 2025)[7]	94 HTE PWH with RAMs to ≥1 ARV of 2 major drug classes; 49 patients (52%) were virologically suppressed at LEN + OBR initiation	• VL <50 c/mL at last visit (median, 13 mo):
		  • 94% of patients (46/49) with BL VL <50 c/mL
		  • 64% of patients (29/45) with BL VL ≥50 c/mL
		  • Overall, 7% (7/94) had VF and 13% (12/94) had virologic nonresponse; plasma PK assessment in 11 of these 19 patients showed adequate LEN concentrations in 27/35 assessed samples
		• 1 patient developed a LEN RAM (ie, N74D)
			• 12 patients (12.8%) discontinued (VF, n=4; LTFU, n=3; deaths unrelated to drug, n=3; cutaneous side effects, n=1; patient's decision, n=1)

Retrospective, real-world study in the US (Ogbuagu 2026)[8]	93 HTE PWH with a history of resistance and high levels of comorbidities and polypharmacy who initiated LEN	• Rates of VL <50 c/mL and <200 c/mL increased from 36% and 48%, respectively, at BL (n=93) to 67% and 83% at 18 months (n=30) • After LEN initiation, 22% had fewer agents in their ARV regimen than pre-switch; the most common classes included INSTI (69.9%), NRTI (52.7%), and NNRTI (43%) • LEN adherence rate was 83.5%, and 22.6% received all maintenance LEN injections between 24 and 28 weeks after the last injection	• LEN was discontinued by 14.1% (13/92) after the first injection, with a median of 183 days to discontinuation • Laboratory markers remained stable through 18 months of follow-up
LENAddOn: a French, retrospective, observational study (Palich, 2025 and 2026)[9,10]	77 PWH who initiated LEN between June 2023 and June 2024. Many had adherence issues and vulnerability factors	• Reasons for LEN initiation included multidrug resistance (63.6%), adherence challenges (35.1%), treatment simplification (27.3%), poor tolerability of oral ART (19.5%), and avoidance of drug-drug interactions (19.5%) • Adherence at 6 months was 94.8% • Adherence at 12 months was 81.8%	•At 6 months, 4 patients discontinued LEN (VF, n=2; LTFU, n=1; death due to metastatic cancer, n=1) •At 12 months, 10 more patients discontinued LEN (insufficient clinical need, n=3; Grade 2 ISR of painful nodules, n=2; LTFU, n=2; death, n=1; neuropsychological and digestive AEs, n=1; VF, n=1) •Through Month 6, ISRs were reported in 41/77 patients (53.2%) after first injection and in 34/73 patients (46.6%) after second injection; 2 Grade 3 ISRs were reported at each time point

French Compassionate Use Program (Delaugerre, 2025)[11]	33 PWH with a history of multidrug failure received LEN SUBQ once every 26 weeks in combination with an OBR	• VL <50 c/mL at Wk 26 (primary endpoint):
		  • 86% of patients (12/14) with BL VL <50 c/mL
		  • 53% of patients (10/19) with BL VL ≥50 c/mL
		• VL <50 c/mL at last follow-up (median, 12.2 mo)
		  • 93% of patients (13/14) with BL VL <50 c/mL
		  • 74% of patients (14/19) with BL VL ≥50 c/mL
		• From BL to Wk 26, 6 patients had VF; 1 patient had a LEN RAM (ie, Q67H)
			• ISRs were reported in 11/33 patients (33%); none led to treatment discontinuation
			• There were no Grade 3 or 4 TRAEs
			• There were 2 deaths: 1 death due to acute hepatitis that led to multiorgan failure at Week 4 and 1 death secondary to septic shock at Week 15

Abbreviations: AE=adverse event; ANRS MIE=Agence Nationale de Recherche sur le Sida et les Hepatites Maladies Infectieuses Émergentes; OPERA=Observational Pharmaco-Epidemiology Research & Analysis; PK=pharmacokinetic(s); VF=virologic failure; VL=viral load.

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Abbreviations

ARV=antiretroviral
ATV=atazanavir
BL=baseline
c/mL=copies/mL
CD4=cluster of differentiation 4
DRV=darunavir
DTG=dolutegravir
FTR=fostemsavir
HIV-SI=HIV Symptom Index
HTE=heavily treatment-experienced
IBA=ibalizumab
INSTI=integrase strand transfer inhibitor
ISR=injection site reaction
LEN=lenacapavir
LTFU=lost to follow-up
M=E=missing equals excluded
MIC=minimal important change
MVC=maraviroc
NNRTI=non-nucleos(t)ide reverse transcriptase inhibitor
NPRS=numeric pain rating scale
NRTI=nucleos(t)ide reverse transcriptase inhibitor
OBR=optimized background regimen
OSS=overall susceptibility score
PBO=placebo
PI=protease inhibitor
PRO=patient-reported outcome
PWH=people with HIV
RAM=resistance-associated mutation
SF-36=36-item Short Form Survey
SUBQ=subcutaneous(ly)
T20=enfuvirtide
TEAE=treatment-emergent adverse event
TRAE=treatment-related adverse event
VAS=visual analogue scale

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Sunlenca US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_pi.

Follow-Up

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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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