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GILEAD | Medical Information

Sunlenca® (lenacapavir) Safety Overview

This document is in response to your request for information regarding the safety of Sunlenca® (lenacapavir [LEN]) in people with HIV-1 (PWH). This response was developed according to principles of evidence-based medicine and contains data from phase 3 clinical trials and real-world studies (N>70).

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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]

The primary safety assessment of LEN was based on data from HTE adult participants with HIV who received LEN in a phase 2/3 trial (CAPELLA; N=72) through Week 52 (median duration on study of 71 weeks), as well as supportive data in TN adult participants with HIV who received LEN in a phase 2 trial (CALIBRATE; N=157) through Week 54 (median duration of exposure of 66 weeks).

The most common adverse reactions (all Grades) reported in ≥3% of participants in CAPELLA were nausea and ISRs.

Clinical Studies on Safety of LEN Use in PWH

In the phase 2/3 CAPELLA study in HTE PWH, no Grade ≥4 or serious TRAEs occurred during follow-up through a median (IQR) of 165 (146–178) weeks.[2,3]

In the phase 2 CALIBRATE study in TN PWH, most laboratory abnormalities observed in participants were Grade 1 or 2 in severity, and there were no serious TRAEs reported through the last study visit (up to Week 184).[4]

ISRs were reported in 63%, 46%, and 55% of participants in CAPELLA and 42%, 52%, and 43% of participants in CALIBRATE after the first, second, and third SUBQ LEN injections, respectively. The majority of these ISRs were Grade 1 or 2 in severity, and no Grade 4 ISRs were reported. Five participants discontinued SUBQ LEN due to ISRs.[5] The frequency of ISRs decreased over time in both studies.[4,6]

Real-World Data on Safety of LEN Use in PWH

In LENAddOn, an observational, retrospective study in France (N=77), ISRs were reported by 53.2% and 46.6% after the first and second SUBQ LEN injections, respectively. Two Grade 3 ISRs (pain ± erythema) were reported after the first SUBQ LEN injection and did not lead to LEN discontinuation. Two additional Grade 3 ISRs were reported after the second injection at Month 6.[7]

Product Labeling[1]

Warnings and Precautions

Immune reconstitution syndrome

Immune reconstitution syndrome has been reported in patients treated with combination ARV therapy. During the initial phase of combination ARV treatment, patients whose immune system responds may develop an inflammatory response to indolent or residual opportunistic infections (such as *Mycobacterium avium* infection, cytomegalovirus, *Pneumocystis jirovecii* pneumonia, or tuberculosis), which may necessitate further evaluation and treatment.

Autoimmune disorders (such as Graves' disease, polymyositis, Guillain-Barré syndrome, and autoimmune hepatitis) have also been reported to occur in the setting of immune reconstitution; however, the time to onset is more variable, and can occur many months after initiation of treatment.

Long-acting properties and potential associated risks with LEN

Residual concentrations of LEN may remain in the systemic circulation of patients for prolonged periods (up to 12 months or longer after the last SUBQ dose). It is important to counsel patients that maintenance dosing by injection is required every 6 months, because missed doses or non-adherence to injections could lead to loss of virologic response and development of resistance.

LEN, a moderate CYP3A inhibitor, may increase the exposure to, and therefore potential risk of adverse reactions from, drugs primarily metabolized by CYP3A initiated within 9 months after the last SUBQ dose of LEN.

If LEN is discontinued, to minimize the potential risk of developing viral resistance, it is essential to initiate an alternative, fully suppressive ARV regimen where possible no later than 28 weeks after the final injection of LEN. If virologic failure occurs during treatment, switch the patient to an alternative regimen if possible.

ISRs

Administration of LEN may result in local ISRs. If clinically significant ISRs occur, evaluate and institute appropriate therapy and follow-up.

Manifestations of ISRs may include swelling, pain, erythema, nodule, induration, pruritus, extravasation, or mass. Nodules and indurations at the injection site may take longer to resolve than other ISRs. In clinical studies, after a median follow-up of 553 days, 30% of nodules and 13% of indurations (in 10% and 1% of participants, respectively) associated with the first injections of LEN had not fully resolved. Measurements and qualitative assessments of ISRs were not routinely reported. Where described, the majority of the injection site nodules and indurations were palpable but not visible, and had a maximum size of approximately 1 to 4 cm.

The mechanism driving the persistence of injection site nodules and indurations in some patients is not fully understood, but based on available data, they may be related to the presence of the SUBQ drug depot. In some patients who had a skin biopsy performed of an injection site nodule or induration, dermatopathology revealed foreign body inflammation or granulomatous response.

Improper administration (intradermal injection) has been associated with serious ISRs, including necrosis and ulcer. Ensure LEN is only administered SUBQ in the abdomen.

Adverse Reactions

Clinical trials experience

The most common adverse reactions (all grades) reported in ≥3% of participants in CAPELLA were nausea and ISRs. The proportion of participants in CAPELLA who discontinued treatment with LEN due to AEs, regardless of severity, was 1% (Grade 1 injection site nodule in 1 participant).

The majority (96%) of all adverse reactions associated with LEN were mild or moderate in severity.

Laboratory abnormalities

The frequency of laboratory abnormalities (Grades 3 to 4) occurring in ≥2% of participants in CAPELLA are presented in Table 1.

Table 1. Selected Laboratory Abnormalities (Grades 3 to 4) Reported in ≥2% of Participants Receiving LEN in CAPELLA (Week 52 Analysis)[1]

Laboratory Parameter Abnormality, %	LEN + Background Regimen (N=72)[a]
Cr >1.8 × ULN or ≥1.5 × baseline level	13
Glycosuria (>2+)[b]	6
Hyperglycemia, fasting (>250 mg/dL)	5
Proteinuria (>2+)[b]	4
ALT ≥5 × ULN[b]	3
AST ≥5 × ULN	3
Direct bilirubin >ULN[b]	3

Abbreviation: ULN=upper limit of normal.

[a]Frequencies are based on treatment-emergent laboratory abnormalities in all participants (Cohorts 1 and 2) in CAPELLA. Percentages were calculated based on the number of participants with post-baseline toxicity grades for each laboratory parameter (n=72 for all parameters except fasting hyperglycemia, n=57).

[b]Grade 3 only (no Grade 4 values reported).

Postmarketing experience

In addition to adverse reactions reported from clinical trials, injection site necrosis was identified during postmarketing use. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

For full safety information, please refer to the LEN US Prescribing Information Sections 5 and 6.

Clinical Studies on Safety of LEN Use in PWH

CAPELLA and CALIBRATE Studies

Study design and demographics

CAPELLA (NCT04150068) is an ongoing, randomized, placebo-controlled, phase 2/3 clinical study of SUBQ LEN in combination with OBR in HTE PWH with multidrug resistance. Participants receiving SUBQ LEN started with an oral LEN initiation phase (Day 1, 600 mg; Day 2, 600 mg; Day 8, 300 mg), followed by SUBQ LEN 927 mg (2 × 1.5 mL) administered in the maintenance phase on Day 15 and every 6 months thereafter with OBR.[8]

CALIBRATE was a randomized, open-label, active-controlled, phase 2 study of LEN in combination with other ARVs vs BIC/FTC/TAF in TN PWH. Participants were randomized to one of four treatment groups: SUBQ LEN + FTC/TAF→TAF (Group 1), SUBQ LEN + FTC/TAF→BIC (Group 2), oral LEN + FTC/TAF (Group 3), or BIC/FTC/TAF alone (Group 4).[3] Participants receiving SUBQ LEN started with an oral LEN initiation phase (Day 1, 600 mg; Day 2, 600 mg; Day 8, 300 mg), followed by SUBQ LEN 927 mg (2 × 1.5 mL) on Day 15 and every 26 weeks thereafter. The dosing schedule in the oral LEN group consisted of the following: Day 1, 600 mg; Day 2, 600 mg; Day 3 and thereafter, 50 mg daily.[9,10]

Table 2. CAPELLA and CALIBRATE: Baseline Demographics and Characteristics[11,12]

Key Demographics and Characteristics[a]		CAPELLA (N=72)	CALIBRATE (N=182)
Age, median (IQR), y		52 (45–59)	29 (19–72)
Female sex at birth, %		25	7
Race or ethnicity,[b] %	Black	38	52
	White	41	NR
	Asian	21	NR
	Hispanic/Latinx	21	45
Viral load[c]	HIV-1 RNA, median (IQR), log_{10} c/mL	4.5 (3.5–4.9)	4.37 (NR)
	>100,000 c/mL, %	19	15
CD4 count	Median (IQR), cells/mcL	150 (76–286)	437 (NR)
	<200 cells/mcL, %	64	2

Abbreviations: CD4=cluster of differentiation-4; NR=not reported.
[a]Percentages may not equal 100 due to rounding.
[b]Race was reported by participants in CAPELLA. Collection of race or ethnicity data was prohibited by local regulators for 1 participant in the placebo group and was excluded from the denominator of the % calculation.
[c]Two participants in the nonrandomized CAPELLA cohort had HIV-1 RNA >400 c/mL at screening but <50 c/mL at enrollment.

Safety: CAPELLA study

Safety results through Week 156 are summarized in Table 3. No Grade 4 or serious TRAEs occurred. Median (IQR) duration of follow-up was 165 (146–178) weeks.[2]

Table 3. CAPELLA: Safety Results Through Week 156 (Excluding ISRs)[2]

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

[a]Included ISRs (n=4), abdominal abscess (n=1), immune reconstitution inflammatory syndrome (n=1), and rash (n=1).
[b]Due to acute respiratory failure, cancer, and unknown cause (each, n=1); none was considered treatment related.

Abnormal laboratory results in CAPELLA through Week 156 are summarized in Table 4.[2,3]

Table 4. CAPELLA: Grade 3 or 4 Laboratory Abnormalities Through Week 156[2,3]

Laboratory Abnormalities, n/N (%)		Total (N=72)
Any Grade 3 or 4 laboratory abnormality		29/72 (40.3)[a]
Grade 3 or 4 laboratory abnormalities that occurred in ≥5% of participants	Low CrCl	19/72 (26.4)
	High Cr	14/72 (19.4)
	Glycosuria	6/72 (8.3)
	Nonfasting hyperglycemia	5/67 (7.5)
	Proteinuria	5/72 (6.9)
	Fasting hyperglycemia	4/65 (6.2)
	High ALT	4/72 (5.6)
	High AST	4/72 (5.6)

[a]Thirteen participants had the following Grade 4 laboratory abnormalities: elevated Cr (n=5), low CrCl (n=5), elevated AST (n=3), elevated ALT (n=1), fasting hyperglycemia (n=1), nonfasting hyperglycemia (n=1), elevated creatine kinase (n=1), and elevated lipase (n=1). The following abnormalities were transient, were not considered clinically significant, and were potentially related to underlying conditions: high Cr levels, low CrCl, and hyperglycemia.

Safety: CALIBRATE study

The safety analysis included data collected up to each participant's last study visit up to Week 184. Most laboratory abnormalities observed in participants were Grade 1 or 2 in severity. Grade 3 or 4 laboratory abnormalities observed through the last study visit are summarized in Table 5.[9]

Table 5. CALIBRATE: Grade 3 or 4 Laboratory Abnormalities Through Last Study Visit[4,13]

Laboratory Abnormalities, n (%)	Group 1: SUBQ LEN + FTC/TAF→TAF (n=52)	Group 2: SUBQ LEN + FTC/TAF→BIC (n=53)	Group 3: Oral LEN + FTC/TAF (n=52)	Group 4: BIC/FTC/TAF (n=25)
Any grade	50 (96)	52 (98)	50 (96)	25 (100)
Grade 1	5 (10)	2 (4)	5 (10)	0
Grade 2	29 (56)	30 (57)	22 (42)	19 (76)

Laboratory Abnormalities, n (%)	Group 1: SUBQ LEN + FTC/TAF→TAF (n=52)	Group 2: SUBQ LEN + FTC/TAF→BIC (n=53)	Group 3: Oral LEN + FTC/TAF (n=52)	Group 4: BIC/FTC/TAF (n=25)
Grade 3	9 (17)	15 (28)	16 (31)	6 (24)
Grade 4	7 (14)	5 (9)	7 (14)	0

Through the last study visit, no serious TRAEs were reported. Rates of AEs, excluding ISRs, are shown in Table 6. A TEAE of viral load increase led to LEN discontinuation in 1 participant in Group 1.[9]

Table 6. CALIBRATE: Safety Results Through Last Study Visit (Excluding ISRs)[4]

Safety Parameters, n or n (%)		Group 1: SUBQ LEN + FTC/TAF→TAF (n=52)	Group 2: SUBQ LEN + FTC/TAF→BIC (n=53)	Group 3: Oral LEN + FTC/TAF (n=52)	Group 4: BIC/FTC/TAF (n=25)
Any TEAE		51 (98)	47 (89)	47 (90)	21 (84)
Grade ≥3		6 (12)	5 (9)	10 (19)	2 (8)
TEAEs that occurred in ≥15% of participants in any group (excluding ISRs)	Influenza	13 (25)	5 (9)	11 (21)	0
	COVID-19	10 (19)	9 (17)	11 (21)	4 (16)
	Headache	10 (19)	8 (15)	9 (17)	3 (12)
	Nausea	10 (19)	5 (9)	7 (14)	1 (4)
	Nasopharyngitis	9 (17)	6 (11)	5 (10)	0
	Syphilis	8 (15)	9 (17)	7 (14)	4 (16)
	URTI	8 (15)	1 (2)	7 (14)	3 (12)
	Diarrhea	7 (14)	6 (11)	8 (15)	2 (8)
	Arthralgia	5 (10)	5 (9)	7 (14)	4 (16)
Any TRAE		42 (81)	32 (60)	8 (15)	4 (16)
Grade ≥3		1 (2)	1 (2)	0	0
Serious TEAEs		4 (8)[a]	4 (8)[b]	7 (14)[c]	0
Deaths		1[d]	0	1[e]	0

Abbreviation: URTI=upper respiratory tract infection.
[a]Included cholecystitis, diabetic ketoacidosis, dyspnea, lymphadenopathy mediastinal, metastases to central nervous system, non-small cell lung cancer, pleural effusion, pneumonia, *Staphylococcal* infection, uterine leiomyoma, and vomiting.
[b]Included deep vein thrombosis, *Escherichia* infection, hepatitis A, injury, loss of personal independence in daily activities, perirectal abscess, postprocedural complication, and substance-induced psychotic disorder.
[c]Included appendicitis, bipolar disorder, death, major depression, mental disorder, *Pneumocystis jirovecii* pneumonia, pneumothorax, poisoning, psychotic disorder, and rhabdomyolysis.
[d]Due to non-small cell lung cancer; not considered related to study drug.
[e]Due to unknown causes; not considered related to study drug.

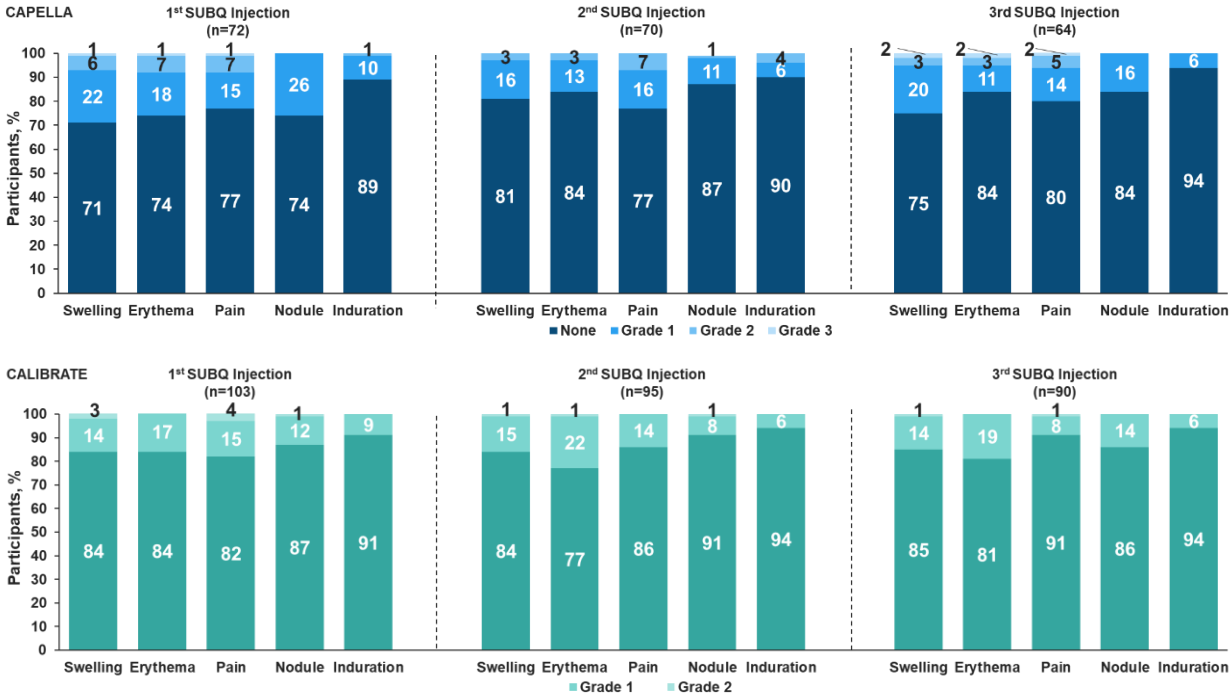
SUBQ LEN-related ISRs

SUBQ LEN-related ISRs in CAPELLA and CALIBRATE through first three injections[5]

An analysis of ISRs was conducted in 175 participants who received ≥1 dose of SUBQ LEN in CAPELLA (N=72) and CALIBRATE (n=103). Participants in CAPELLA received a median (IQR) of 10 (8–10) injections with a median (IQR) duration of exposure of 125 (111–140) weeks, and participants in CALIBRATE had a median (IQR) of 6 (6–8) injections with a median (IQR) duration of exposure of 88 (83–107) weeks. In both studies, SUBQ LEN 927 mg (2 × 1.5 mL) was administered into the abdomen every 6 months.

ISRs were reported in 63%, 46%, and 55% of participants in CAPELLA and 42%, 52%, and 43% of participants in CALIBRATE after the first, second, and third SUBQ LEN injections, respectively. Figure 1 shows the frequency and severity of the most common ISRs related to SUBQ LEN in CAPELLA and CALIBRATE. The majority of ISRs were Grade 1 or 2 in severity, and no Grade 4 ISRs were reported. Five participants discontinued SUBQ LEN due to ISRs.

Figure 1. CAPELLA and CALIBRATE: ISRs After the First Three Injections[5a]



[a]Percentages are based on participants who received an injection at the respective visit; percentages may not total 100% because of rounding.

The durations of the most common ISRs in each study are presented in Table 7.

Table 7. CAPELLA and CALIBRATE: Durations of ISRs After the First Three Injections[5]

Duration, Median (IQR), Days	CAPELLA (N=72)	CALIBRATE (N=103)
Nodule	252 (113–524)	250 (100–369)
Induration	183 (63–498)	215 (144–415)
Swelling	8 (4–15)	11 (6–15)
Erythema	5 (3–8)	5 (2–11)
Pain	3 (1–4)	2 (1–6)

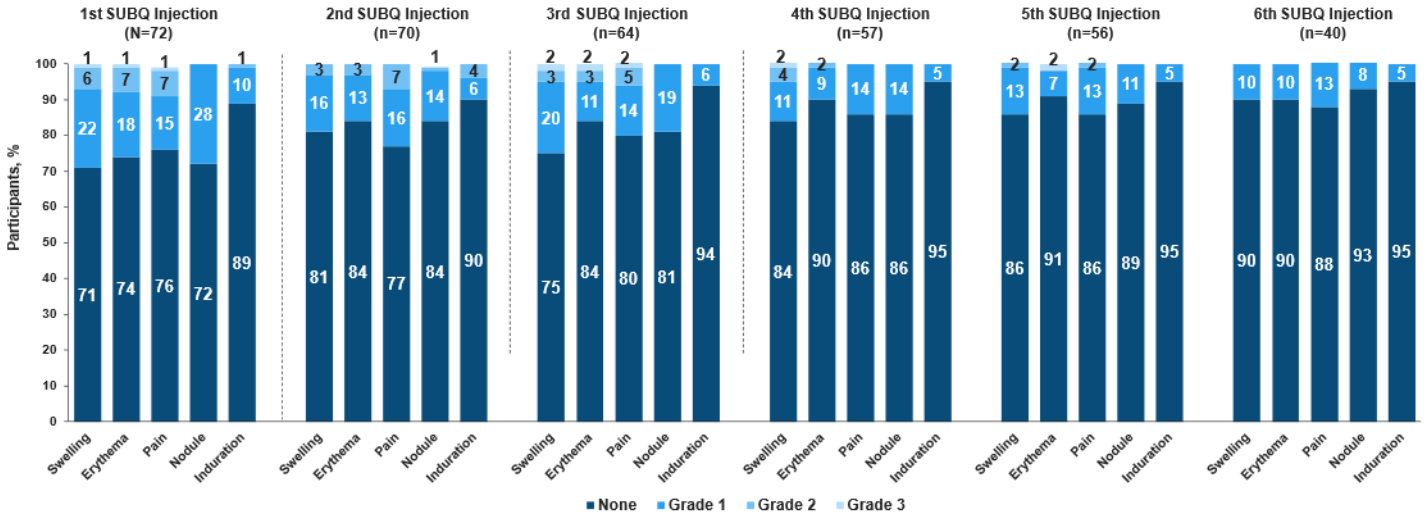
One participant in CAPELLA and 4 participants in CALIBRATE discontinued SUBQ LEN due to ISRs (Grade 1 induration, n=3; Grade 1 nodule, n=1; Grade 1 erythema and swelling, n=1), and only 1 discontinuation occurred after the first year of follow-up.

SUBQ LEN-related ISR data: CAPELLA results through Week 156 (sixth injection)[2]

Most ISRs (97.2%) reported through Week 156 were Grade 1 or 2 in severity, and the frequency of ISRs reduced over time (Figure 2). The median (IQR) duration of swelling, erythema, pain, nodules, and induration was 8 (4–15), 5 (3–8), 3 (2–5), 288 (155–548), and

190 (67–410) days, respectively. Grade 1 ISRs of injection site nodules led to study discontinuation in 2 participants.

Figure 2. CAPELLA: ISRs Related to SUBQ LEN Through Sixth Injection at Week 156[2,3a]

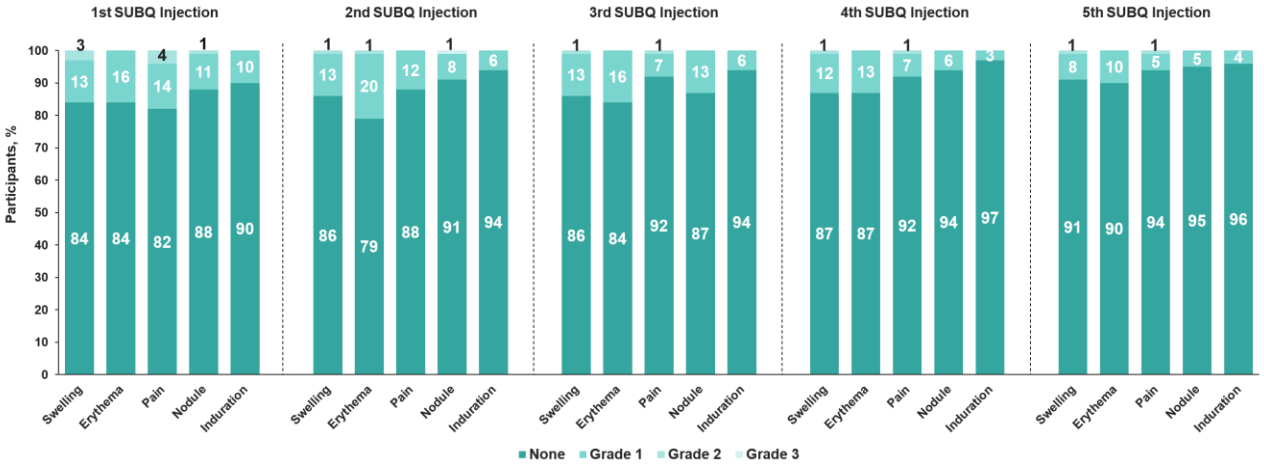


[a]Percentage denominators are the number of participants who received an injection at that visit. Percentages may not total 100% due to rounding.

SUBQ LEN-related ISR data: CALIBRATE results up to Week 184 (fifth injection)[4]

The median (IQR) duration of exposure to LEN + ARVs was 156 (147–172) weeks in Group 1 and 154 (118–164) weeks in Group 2. Through Week 132, 103 participants overall received ≥1 SUBQ LEN injection (Group 1, n=51; Group 2, n=52); of these, 69 participants (67%) reported an ISR of any grade. The frequency of LEN-related ISRs decreased over time, with reports of 43% after the first injection visit, 52% after the second, 46% after the third, 32% after the fourth, and 30% after the fifth. Most ISRs were Grade 1 or 2 in severity (Figure 3). The median (IQR) duration of swelling, erythema, pain, induration, and nodule was 10 (5–15), 5 (2–9), 2 (1–6), 192 (143–400), and 219 (84–372) days, respectively. Overall, LEN discontinuations were reported in 3 participants due to Grade 1 injection site induration and in 1 participant due to both Grade 1 injection site erythema and Grade 1 injection site swelling.

Figure 3. CALIBRATE Study: ISRs Related to SUBQ LEN After the First Five Injections (Treatment Groups 1 and 2, n=105)[4]



Note: The denominator was 105, which included 2 participants who did not receive a LEN SUBQ injection. LEN SUBQ injection 1 occurred at Day 15, injection 2 at Week 28, injection 3 at Week 54, injection 4 at Week 80, and injection 5 at Week 106.

Real-World Data on Safety of LEN Use in PWH

LENAddOn Study[7]

LENAddOn is an observational, retrospective, multicenter study in France that aims to characterize PWH who initiate LEN in the commercial setting, assess LEN continuation rates at Months 6 and 12, and describe reasons for LEN discontinuation (N=77). The median (IQR) age is 57 (44–63) years, 67.5% are cisgender men, the median (IQR) time from HIV diagnosis was 30 (21–34) years, and 61% have had an AIDS-defining event. Overall, 21 participants (27.3%) received a fully injectable ARV regimen (LEN + CAB, n=16; LEN + CAB + RPV, n=5).

After the first SUBQ LEN injection, ISRs were reported for 53.2% of participants (41/77), of which 26% were Grade 1, 24% were Grade 2, and 3% were Grade 3. The 2 Grade 3 ISRs were pain ± erythema and did not lead to LEN discontinuation. No other Grade ≥3 biological or clinical AEs were reported in between the first and second SUBQ LEN injections. There were 4 LEN discontinuations after the first injection: persistence of viral replication (n=2), lost to follow-up (n=1), and death due to cancer (n=1). After the second SUBQ LEN injection at Month 6, ISRs were reported for 46.6% of participants (34/73); 22% of these ISRs were Grade 1, 22% were Grade 2, and 3% were Grade 3. No additional information was provided on the 2 Grade 3 ISRs at Month 6.

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Abbreviations

AE=adverse event
ARV=antiretroviral
BIC=bictegravir
c/mL=copies per mL
CAB=cabotegravir
FTC=emtricitabine
HTE=heavily treatment-experienced
ISR=injection site reaction
LEN=lenacapavir
OBR=optimized background regimen
PWH=people with HIV-1
RPV=rilpivirine
SAE=serious adverse event
SUBQ=subcutaneous(ly)
TAF=tenofovir alafenamide
TEAE=treatment-emergent adverse event
TN=treatment naive
TRAE=treatment-related adverse event

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

For any additional questions, please contact Gilead Medical Information at:

☎1-866-MEDI-GSI (1-866-633-4474) or 🖱 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 www.gilead.com/utility/contact/report-an-adverse-event

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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