GILEAD | Medical Information

Sunlenca® (lenacapavir) Coadministration with Ibalizumab

This document is in response to your request for information regarding Sunlenca® (lenacapavir [LEN]) and coadministration with ibalizumab (IBA).

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

Summary

Product Labeling

LEN, a HIV-1 capsid inhibitor, is indicated:

- in combination with other ARV(s) 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.
- for oral loading as a component of the initiation regimen for BIC/LEN, a complete regimen for the treatment of HIV-1 infection, in adults to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 c/mL) on a stable ARV with no known or suspected resistance to the individual components of BIC/LEN.

Concomitant administration of LEN with strong CYP3A inducers is contraindicated due to decreased LEN plasma concentrations, which may result in the loss of therapeutic effect and development of resistance to LEN.[1]

Phase 2/3 Study

CAPELLA (GS-US-200-4625) is a phase 2/3 study that evaluated LEN in combination with other ARV drug classes, including entry inhibitors.[2,3]

Real-World Data on LEN and Coadministration with IBA

A retrospective observational case series assessed medical charts from PWH with multidrug resistant HIV-1 that used a combination of both IBA + LEN ± OBR for at least 6 months.[13]

Product Labeling[1]

LEN, a HIV-1 capsid inhibitor, is indicated:

- in combination with other ARV(s) 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.
- for oral loading as a component of the initiation regimen for BIC/LEN, a complete regimen for the treatment of HIV-1 infection, in adults to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 c/mL) on a stable ARV with no known or suspected resistance to the individual components of BIC/LEN.

Concomitant administration of LEN with strong CYP3A inducers is contraindicated due to decreased LEN plasma concentrations, which may result in the loss of therapeutic effect and development of resistance to LEN.

Effect of Other Drugs on LEN

Drugs that are strong or moderate inducers of CYP3A may significantly decrease plasma concentrations of LEN, which may result in loss of therapeutic effect of LEN and development of resistance. Concomitant administration of LEN with strong CYP3A inducers during LEN treatment is contraindicated. Concomitant administration of LEN with moderate CYP3A inducers during LEN treatment is not recommended.

Combined P-gp, UGT1A1, and strong CYP3A inhibitors may significantly increase plasma concentrations of LEN. Concomitant administration of LEN with these inhibitors is not recommended.

Effect of LEN on Other Drugs

LEN is a moderate inhibitor of CYP3A. Due to the long half-life of LEN following subcutaneous administration, LEN may increase the exposure of drugs primarily metabolized by CYP3A initiated within 9 months after the last subcutaneous dose of LEN, which may increase the potential risk of adverse reactions. See the prescribing information of the sensitive CYP3A substrate for dosing recommendations with moderate inhibitors of CYP3A.

Phase 2/3 Studies

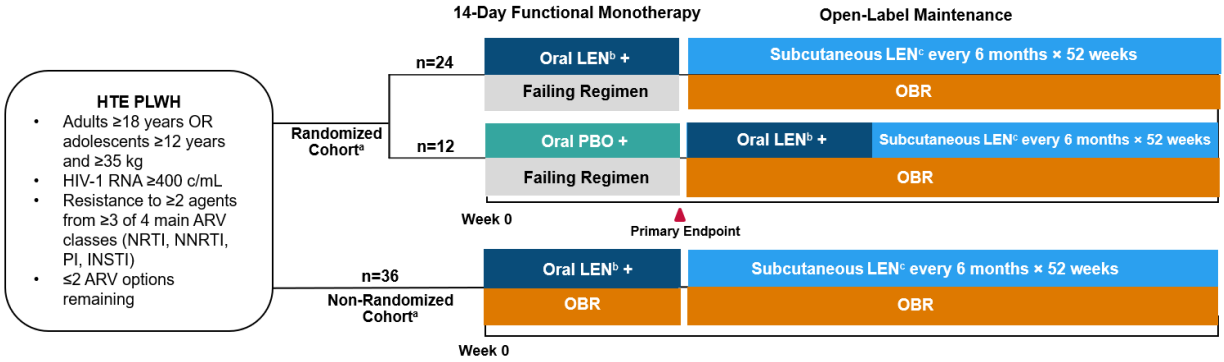
CAPELLA

Study Design and Coadministered ARVs

CAPELLA (GS-US-200-4625) is a phase 2/3, double-blinded, PBO-controlled clinical study designed to evaluate LEN as add-on therapy to a failing regimen in HTE PLWH with multidrug resistance. Participants on a failing regimen for ≥8 weeks who met the inclusion criteria entered a screening period. Those without a prespecified decline in viral load or change in HIV-1 RNA during the screening period were randomly assigned to receive either oral LEN or PBO in addition to their existing failing regimen. After this functional monotherapy phase, participants entered the open-label maintenance phase with

subcutaneous LEN and a possible change in their failing regimen to OBR. Participants in the screening period who experienced prespecified improvements in HIV-1 RNA or who were enrolled after the randomized cohort was fully recruited, were enrolled into the nonrandomized cohort (Figure 1).[2,3]

Figure 1. CAPELLA: Study Design[2,3]



Note: ATV, ATV/COBI, ATV/ritonavir, efavirenz, etravirine, nevirapine, and tipranavir were not permitted for use in OBR.[4]
[a]Participants with <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 nonrandomized cohort if they had ≥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]Subcutaneous LEN dosing schedule: 927 mg (2× 1.5 mL) on Day 15 and then every 6 months.

Baseline characteristics are provided in Table 1.[5,6] Twenty-two percent of all participants (16/72) did not have changes in their OBR before they entered the open-label maintenance phase. An overview of ARV drug classes/agents used concomitantly with LEN in this study are provided in Table 2.[7,8]

Table 1. CAPELLA Study: Baseline Demographics and Disease Characteristics[5,6]

Key Demographics and Characteristics*	Randomized Cohort		Non-Randomized Cohort	Total (N=72)
	LEN (n=24)	PBO (n=12)	LEN (n=36)	
Age, median (range), y	55 (50–61)	54 (49–55)	49 (38–60)	52 (45–59)
Female at birth, n (%)	7 (29)	3 (25)	8 (22)	18 (25)
Race†				
Black, n (%)	10 (42)	6 (50)	11 (31)	27 (38)
White, n (%)	12 (50)	4 (36)	13 (36)	29 (41)
Asian, n (%)	2 (8)	1 (9)	12 (33)	15 (21)
Data could not be collected, n (%)	0	1 (9)	0	1 (1)
Hispanic or Latinx ethnicity, n (%)	6 (25)	4 (36)	5 (14)	15 (21)
Viral load‡				
HIV RNA, mean±SD, log_{10} c/mL	3.97±0.92	4.87±0.39	4.06±1.16	4.17±1.03
HIV RNA, median (range), 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				
Mean±SD, cells/ µL	199±166	85±63	258±273	210±224
Median (range), cells/µL	172 (99–248)	85 (39–109)	195 (56–392)	150 (76–286)

Key Demographics and Characteristics*	Randomized Cohort		Non-Randomized Cohort	Total (N=72)
	LEN (n=24)	PBO (n=12)	LEN (n=36)	
Distribution				
<50 cells/µL, n (%)	3 (13)	4 (33)	9 (25)	16 (22)
50 to <200 cells/µL, n (%)	13 (54)	7 (58)	10 (28)	30 (42)
200 to <500 cells/µL, n (%)	7 (29)	1 (8)	12 (33)	20 (28)
≥500 cells/µL, n (%)	1 (4)	0	5 (14)	6 (8)
Number of prior ARV regimens, median (range)	9 (2–24)	9 (3–22)	13 (3–25)	11 (2–25)
Known resistance to ≥2 drugs in class				
NRTI, n (%)	23 (96)	12 (100)	36 (100)	71 (99)
NNRTI, n (%)	22 (92)	12 (100)	36 (100)	70 (97)
PI, n (%)	20 (83)	8 (67)	30 (83)	58 (81)
INSTI, n (%)	20 (83)	7 (58)	23 (64)	50 (69)
All four major classes n (%)	14 (58)	3 (25)	16 (44)	33 (46)
Resistance to entry inhibitors				
T20, n/N (%)	2/23 (9)	3/10 (30)	0/25 (0)	5/58 (9)
Fostemsavir, n/ N (%)	5/23 (22)	5/10 (50)	7/21 (33)	17/54 (31)
IBA, n/N (%)	8/23 (35)	3/10 (30)	6/25 (24)	17/58 (29)
MVC, n/N (%)	19/24 (79)	8/11 (73)	14/26 (54)	41/61 (67)

*Percentages may not equal to 100 due to rounding. †Race was reported by the participants. 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. ‡Two participants in the non-randomized cohort had HIV-1 RNA >400 c/mL at screening but <50 c/mL at enrollment.

Table 2. CAPELLA: Drug Classes/Agents, Number of Fully Active ARV Agents, and OSS in Failing Regimens and OBR[7]

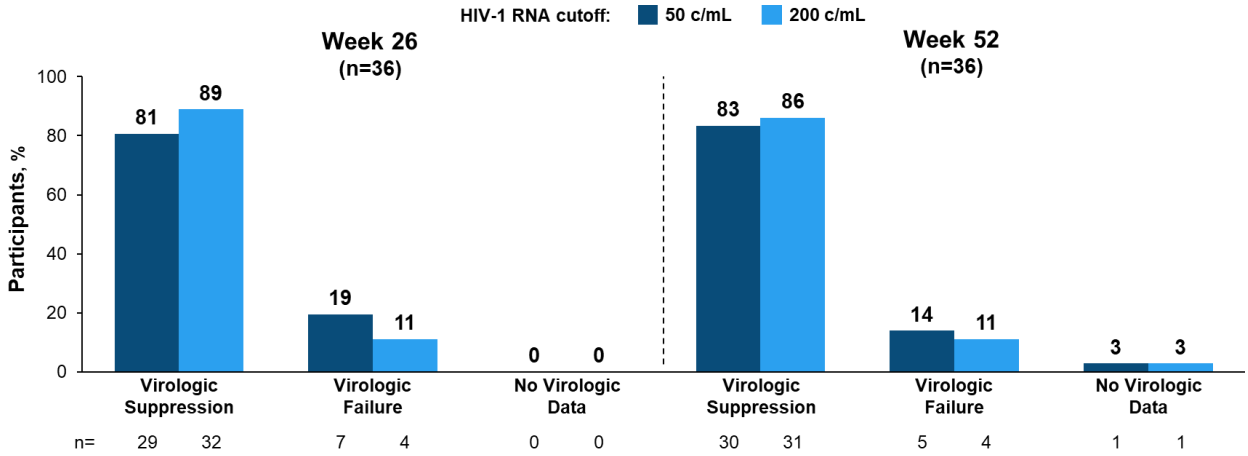
	Failing Regimen (n=72)	OBR (n=72)
Drug class/agent		
NRTI, %	82	85
INSTI, %	68	65
PI, %	63	63
NNRTI, %	31	35
IBA, %	19	24
MVC, %	14	14
Fostemsavir, %	6	11
T20, %	6	7
Number of fully active ARV agents, 0/1/≥2, %	42/36/22	17/38/46
OSS,* median	1	2

*OSS 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 total sum of the individual scores.

Randomized Cohort Efficacy for the Open-Label Maintenance Phase

At Weeks 26 and 52, virologic suppression occurred in a high proportion of participants receiving LEN in addition to an OBR (Figure 2).[6]

Figure 2. CAPELLA Study: Efficacy Results in the Randomized Cohort at Weeks 26 and 52[2,6]



Subgroup Analyses of Efficacy in the Randomized Cohort at Week 26 and 52

Several prespecified subgroup analyses in the randomized cohort (n=36) were conducted to determine the efficacy of LEN at Weeks 26 and 52 according to selected characteristics including baseline use of ARV agents. Efficacy by baseline use of IBA is provide in Table 3.[5,7,9]

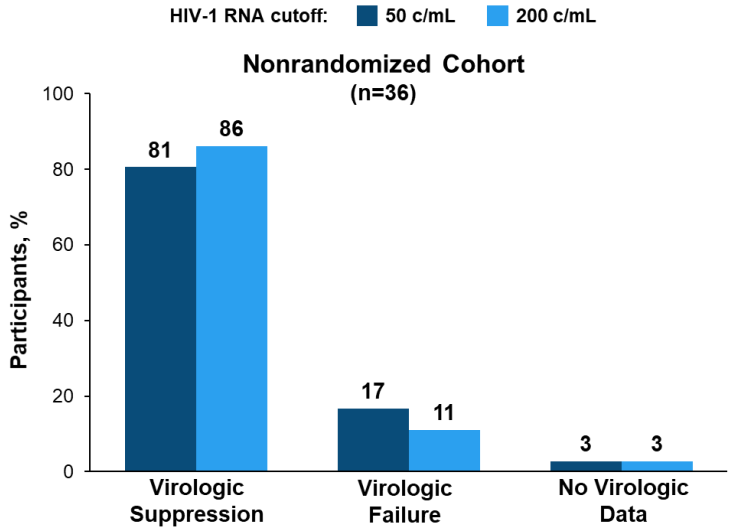
Table 3. CAPELLA Study: Randomized Cohort Subgroup Analyses at Week 26 and 52 of Efficacy by Baseline Use of IBA[5,7,9]

Subgroups	n Per Subgroup	Week 26	Week 52
		Participants with HIV-1 RNA <50 c/mL, %	Participants with HIV-1 RNA <50 c/mL, %
Baseline use of IBA			
Yes	12	75	83
No	24	83	83

Non-Randomized Cohort Efficacy at Week 26

At Week 26, virologic suppression occurred in a high proportion of participants in the non-randomized cohort (Figure 3).[6]

Figure 3. CAPELLA Study: Efficacy Results in the Non-Randomized Cohort at Week 26[6]



Subgroup Analyses of Efficacy in the Non-Randomized Cohort at Week 26[5]

Several subgroup analyses of the non-randomized cohort (n=36) were conducted to determine the efficacy of LEN at Week 26 according to selected characteristics including baseline use of ARV agents. Efficacy by baseline use of IBA is provide in Table 4.

Table 4. CAPELLA Study: Non-Randomized Cohort Subgroup Analyses of Efficacy at Week 26 by Baseline Use of IBA[5]

Subgroups	n Per Subgroup	Participants with HIV-1 RNA <50 c/mL, %
Baseline use of IBA		
Yes	5	60
No	31	87

Post-baseline resistance analyses[8,10]

Nine participants developed CAI resistance through W52 in the randomized and nonrandomized cohorts. Of these, 3 participants had an OBR without any fully active ARVs that included IBA (Table 5).

Table 5. CAPELLA Study: Post-baseline CA Resistance in Participants with OBR containing IBA (Week 52 Interim Analysis)[10]

Pt.	First Visit With CAI Resistance (CAI RAMS)	LEN Susceptibility: Fold Change from WT	Number of Fully Active Agents in OBR	Cohort	Comments
1	Week 4 (M66M/I)	46	0	R	• Functional LEN monotherapy* • Incoming ARVs: FTC (not active), IBA (not active), and TAF (partially active)

Pt.	First Visit With CAI Resistance (CAI RAMS)	LEN Susceptibility: Fold Change from WT	Number of Fully Active Agents in OBR	Cohort	Comments
					• The OBR (FTC, IBA, TAF, DRV/r, and DTG) did not contain any fully active ARVs (only TAF was partially active) • Participant did not achieve HIV RNA <50 c/mL through Week 56
2	Week 4 (M66M/I, Q67Q/H/N, K70K/R)	12	1†	NR	• Functional LEN monotherapy* • Incoming ARVs: FPV, FTC/TAF, DTG, and IBA (all not active except TAF, which was fully active) • The OBR (continued incoming ARVs) did not contain any fully active ARVs (TAF resistance developed at Week 10)
3	Week 4 (M66I, T107A)	240	0	NR	• Functional LEN monotherapy* • Incoming ARVs: DOR, FTR, and IBA (all not active) • The OBR (continued incoming ARVs) did not contain any fully active ARVs. The participant's HIV-1 RNA levels were suppressed between Weeks 32 and 40 after OBR was changed to LPV, BIC/FTC/TAF, and IBA around Week 25 with only BIC fully active and LPV partially active

Abbreviations: 3TC=lamivudine; DOR=doravirine; DRV/c=darunavir boosted with cobicistat; DRV/r=darunavir boosted with ritonavir; FPV=fosamprenavir; FTC=emtricitabine; LLOQ=lower limit of quantification; LPV=lopinavir; NR=non-randomized; Pt.=participant; R=randomized; RPV=rilpivirine; TAF=tenofovir alafenamide; TDF=tenofovir disoproxil fumarate; WT=wild type.
*LEN was the only fully active agent with adequate drug levels.
†TAF was fully active at baseline but was inactive at Week 10.

Safety Results

Safety results for both the randomized and non-randomized cohorts combined are summarized in Table 6.[6,8,11]

Overall, 11% of participants experienced serious AEs at a median of 54 Weeks (IQR, 44-72; range 13-92); none of these were considered to be study drug-related.[5]

A total of 10 participants experienced non-ISR serious AEs at a median of 498 days (approximately 71 weeks) of follow-up (IQR, 421-612); none of these were considered to be study drug related. Two deaths occurred (malignant neoplasm and acute respiratory failure); both were considered unrelated to the study drug.[8]

The majority of ISRs were classified as Grade 1 or 2 in severity. One ISR (Grade 1 nodule) led to study drug discontinuation at Week 62 (10 weeks after the Week 52 injection).[5] All

nodules were classified as Grade 1, except in 1 participant who experienced 2 AEs of Grade 2 nodules that occurred after the second and third injections (both resolved after 3 days). Two participants each experienced a Grade 3 ISR: 1 had erythema and swelling (events resolved within 8 and 4 days, respectively); the other had pain (resolved in 1 day). No participants experienced Grade 4 ISRs.[6]

Table 6. CAPELLA Study: Safety Outcomes[6,8,11]

AEs	Total LEN (N=72)		
Overall summary of AEs ,* %			
Any grade AE	93		
Grade ≥3 AE	22		
Any grade AE related to study drug	67		
Grade ≥3 AE related to study drug	6		
AE that led to early discontinuation of study drug	1†		
Any grade AEs reported in ≥10% of participants (excluding ISRs),‡ n (%)			
Diarrhea	10 (14)		
Nausea	10 (14)		
Constipation	9 (13)		
COVID-19	9 (13)		
Cough	8 (11)		
Pyrexia	8 (11)		
Grade 3 or 4 Laboratory Abnormalities§	**Total LEN (N=72)**		
Any Grade 3 or 4 laboratory abnormality, n (%)	21 (29)		
Grade 3 or 4 laboratory abnormalities in ≥5% of participants			
Low CrCl/eGFR,‖ n (%)	10 (14)		
High SCr level,‖ n (%)	9 (13)		
Non-fasting or fasting hyperglycemia,¶ n (%)	4 (6)		
Glycosuria,¶ n (%)	4 (6)		
ISRs Related to SUBQ LEN†	**After First SUBQ Dose at Week 1 (N=72)**	**After Second SUBQ Dose at Week 2 (n=70)**	**Duration of Reaction, Median, Days**
Swelling, %	26	13	12
Erythema, %	24	11	6
Pain, %	22	21	3
Nodule %	22	11	180
Induration, %	11	10	118

Abbreviation: COVID-19=coronavirus disease 2019.
*Median duration of exposure, 54 weeks (IQR, 44-72; range, 13-92)
†Injection site nodule.
‡Median duration of follow-up, 498 days (IQR, 421-612).
§At ≥197 days of follow-up in 70 participants and ≥379 days of follow-up in 36 participants. None of the Grade 3 to 4 laboratory abnormalities were considered to be clinically relevant.
‖According to the Division of AIDS scale, Grade 3 CrCl is defined as 30 mL/min to <60 mL/min or a 30% to <50% decrease from baseline level. Grade 3 Cr is defined as >1.8 to <3.5 × the upper limit of normal or an increase of 1.5 to <2 × baseline level. Events of low CrCl/eGFR and high SCr levels were transient in duration or not confirmed.

¶Hyperglycemia and glycosuria were transient in duration, related to pre-existing diabetes, or not confirmed.

Case Series on LEN and Coadministration With IBA in PWH

There are limitations in the interpretation of case reports. Case reports cannot be generalized. Unlike controlled clinical trials, causality cannot be inferred based on uncontrolled observational data. In addition, incidence or prevalence cannot be estimated due to the lack of a representative population sample. Other limitations of case reports include the retrospective design and publication bias.[12] This is not exhaustive of all cases found in literature, and additional cases can be found by conducting a literature search in PubMed or other databases.

A case series assessed medical charts from PWH with multidrug resistant HIV-1 across 8 facilities in the United States. A total of 21 PWH had viral loads and CD4+ counts recorded while using a combination of both LEN + IBA ± optimized background regimen for ≥6 months. Of these 21 PWH, 38.1% had resistance across four drug classes (NRTI, NNRTI, PI, INSTI).[13]

There was a median reduction of −2,710 copies/mL HIV-1 RNA VL observed within a range of 12 to 24 weeks after treatment initiation with combination LEN + IBA treatment. Median increase to CD4+ count was 67.5 cells/mm^3 within a range of 4 to 44 weeks after treatment initiation.[13]

Therapy with LEN + IBA continued for an average of 20 months and 30 months, respectively. Most reported intolerances or side effects were mild or self-limiting and did not require changes to treatment (cough n=1, tenderness at LEN injection sites n=1, mild injection site discomfort/pain n=3, fever/chills/nausea/diarrhea n=1, flushing/itchiness/rash/diarrhea n=1, changes to clotting[a] n=1). Two patients, who were both viremic (VL ≥400 copies/mL) and had 2-class resistance at baseline, discontinued treatment due to reported treatment failure.[13]

Treatment with combined LEN + IBA ± optimized background regimen was shown to be well tolerated and led to clinically significant reductions viral loads and improvements in CD4+ counts.[13]

[a] Ibalizumab was discontinued due to clinician concern of clotting

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Abbreviations

ARV=antiretroviral
ATV=atazanavir
ATV/c=atazanavir boosted by cobicistat
ATV/r=atazanavir boosted by ritonavir
AUC=area under the curve
BIC=bictegravir
COBI=cobicistat
c/mL=copies/mL
DRV=darunavir
DRV/c=darunavir boosted by cobicistat
FTC=emtricitabine

IBA=ibalizumab
INSTI=integrase strand transfer inhibitor
LEN=Lenacapavir
MVC=Maraviroc
NNRTI=non-nucleoside reverse transcriptase inhibitor
NRTI=nucleoside reverse transcriptase inhibitor
OBR=optimized background regimen
OSS=overall susceptibility scores
P-gp=P-glycoprotein
PI=protease inhibitor
PWH=people with HIV
PO=by mouth
SUBQ=subcutaneous
T20=enfuvirtide
TAF=tenofovir alafenamide
UGT1A1=uridine diphosphate glucuronosyltransferase 1A1

Product Label

For the full indication, important safety information, and Boxed Warning(s), please refer to the Sunlenca US Prescribing Information available at: http://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

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Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 https://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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