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Sunlenca® (lenacapavir) Optimized Background Regimens in the CAPELLA Study

This document is in response to your request for information regarding Sunlenca® (lenacapavir [LEN]) and optimized background regimens (OBR) used in the CAPELLA study.

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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.

Product Labeling[1]

Indications and Usage

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.

Clinical Studies

The efficacy and safety of LEN in HTE participants with multidrug resistant HIV-1 is based on 52-week data from CAPELLA, a randomized, placebo-controlled, double-blind, multicenter trial (NCT04150068).

CAPELLA: LEN in HTE PWH

Study Design and Demographics

CAPELLA (NCT04150068) is an ongoing, phase 3, 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 either enrolled in the randomized cohort or the

non-randomized cohort. 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). Both cohorts are part of the maintenance phase evaluating the safety and efficacy of SUBQ LEN administered every 6 months in combination with an OBR.[2]

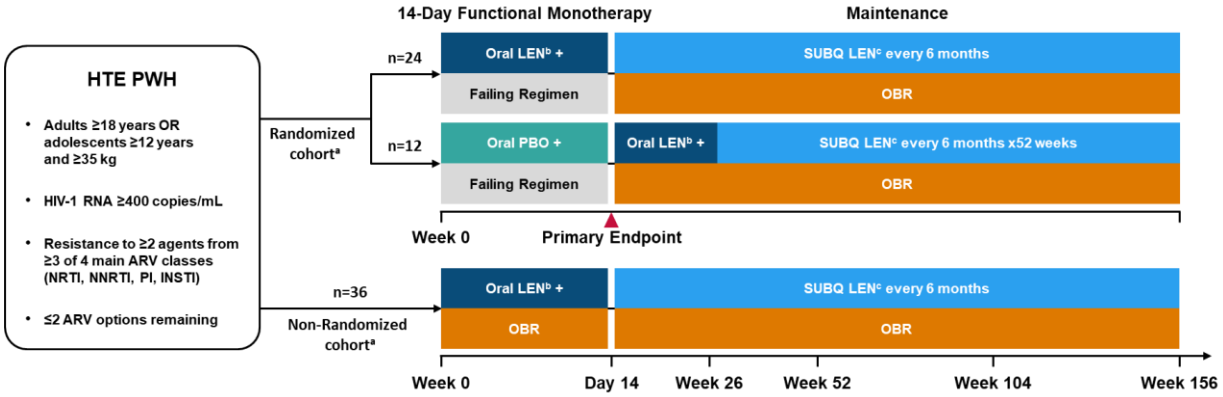


Figure 1. CAPELLA: Study Design[2,3]

Abbreviations: ATV=atazanavir; c=cobicistat; EFV=efavirenz; NVP=nevirapine; r=ritonavir; TPV=tipranavir.
[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 non-randomized 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]SUBQ LEN dosing schedule: 927 mg (2 × 1.5 mL) on Day 15 and then every 6 months.
Note: ATV, ATV/c, 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 baseline to the end of the functional monotherapy phase in the randomized cohort. Secondary endpoints included the percentage of participants in the randomized cohort with HIV-1 RNA <50 c/mL and <200 c/mL at Week 26.[2] Baseline characteristics are provided in Table 1.

Table 1. CAPELLA Study: Baseline Demographics and Disease Characteristics[2a]

Key Demographics and Characteristics		Randomized Cohort		Non-Randomized Cohort	Total (N=72)
		LEN (n=24)	PBO (n=12)	LEN (n=36)	
Age, median (range), years		55 (24–71)	54 (27–59)	49 (23–78)	52 (23–78)
Female at birth, n (%)		7 (29)	3 (25)	8 (22)	18 (25)
HIV RNA viral load[c]	Mean ± SD, log_{10} c/mL	3.97±0.92	4.87±0.39	4.06±1.16	4.17±1.03
	Median (range), log_{10} c/mL	4.2 (2.3–5.4)	4.9 (4.3–5.3)	4.5 (1.3–5.7)	4.5 (1.3–5.7)
	>100,000 c/mL, n (%)	1 (4)	6 (50)	7 (19)	14 (19)
CD4 count	Mean ± SD, cells/mcL	199±166	85±63	258±273	210±224
	Median (range), cells/mcL	172 (16–827)	85 (6–237)	195 (3–1296)	150 (3–1296)
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)
	MVC	19/24 (79)	8/11 (73)	14/26 (54)	41/61 (67)

Key Demographics and Characteristics		Randomized Cohort		Non-Randomized Cohort	Total (N=72)
		LEN (n=24)	PBO (n=12)	LEN (n=36)	
Resistance to EIs, n/N (%)	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)

Abbreviation: CD4=cluster of differentiation 4.
[a]Percentages may not equal to 100 due to rounding.
[b]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.
[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.[4]

Table 2. CAPELLA Study: Composition of Failing Regimens and OBR[5]

		Failing Regimen (N=72)	OBR (N=72)
Drug class or 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

Abbreviation: OSS=overall susceptibility score.
[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 total sum of the individual scores.

Individual OBRs for all 72 participants can be found in Table 3.

Table 3. CAPELLA Study: OBRs for Each Participant (N=72)[6]

Part. ID	Drugs in OBR																
	NRTI					NNRTI			PI		INSTI			EI			
1		FTC		TDF											IBA		
2		FTC		TAF						DRV		DTG			IBA	MVC	T20
3		FTC		TAF						DRV		DTG					
4		FTC		TAF		DOR					BIC					MVC	
5		FTC		TAF		DOR				DRV		DTG					
6		FTC		TAF								DTG					
7		FTC	ABC	TAF						DRV		DTG			IBA		
8		FTC		TAF		DOR					BIC				IBA		T20
9								RPV		DRV		DTG					
10		FTC		TAF						DRV					IBA		
11		FTC		TAF						DRV							
12						DOR				DRV							
13	3TC									DRV		DTG				MVC	T20

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Part. ID	Drugs in OBR																
	NRTI					NNRTI			PI		INSTI			EI			
14		FTC		TAF		DOR					BIC				IBA		
15	3TC							RPV							IBA	MVC	
16		FTC		TAF						DRV							
17		FTC		TAF						DRV							
18		FTC		TAF							BIC				IBA		
19		FTC		TAF							BIC						
20						DOR						DTG					
21		FTC		TAF						DRV		DTG					
22				TDF						DRV		DTG					
23	3TC		ABC									DTG			IBA		
24		FTC		TAF							BIC						
25		FTC	ABC	TDF						DRV							
26		FTC		TAF						DRV		DTG			IBA		
27		FTC		TAF										FTR			
28		FTC		TAF						DRV	BIC					MVC	
29		FTC		TDF						DRV		DTG					
30	3TC			TDF	AZT					DRV							
31		FTC		TAF		DOR				DRV							T20[a]
32	3TC											DTG			IBA	MVC	
33		FTC		TAF								DTG		FTR			
34						DOR						DTG					
35		FTC		TAF						DRV		DTG		FTR	IBA		
36				TDF						DRV		DTG					
37				TDF						DRV		DTG					
38		FTC		TAF		DOR					BIC						
39		FTC		TAF		DOR				DRV							
40						DOR						DTG					
41		FTC		TAF					FPV			DTG			IBA		
42		FTC		TDF								DTG					
43		FTC		TDF						DRV		DTG					
44		FTC		TAF							BIC						
45		FTC		TDF						DRV		DTG					
46		FTC		TAF		DOR				DRV					IBA	MVC	
47	3TC			TDF						DRV							
48		FTC		TAF		DOR				DRV							
49		FTC		TAF						DRV							
50										DRV		DTG					
51		FTC		TAF		DOR				DRV				FTR			
52		FTC		TAF						DRV				FTR			
53										DRV						MVC	
54		FTC		TAF		DOR				DRV							
55		FTC		TAF			ETV			DRV		DTG					T20
56						DOR								FTR	IBA		
57		FTC		TAF						DRV		DTG				MVC	
58										DRV		DTG				MVC	T20
59				TDF						DRV		DTG					
60										DRV		DTG			IBA		
61				TDF						DRV		DTG					
62		FTC		TDF								DTG					
63		FTC		TAF							BIC						
64						DOR						DTG					
65		FTC		TDF						DRV							
66		FTC		TAF				RPV				DTG					
67		FTC		TDF						DRV		DTG					
68		FTC		TAF						DRV	BIC	DTG					
69		FTC		TDF				RPV		DRV			RAL				

Intended for U.S. Healthcare Professionals only
Last Updated: 28 Aug 2026

Part. ID	Drugs in OBR																
	NRTI					NNRTI			PI		INSTI			EI			
70	3TC			TDF		DOR											
71		FTC		TDF										FTR	IBA		
72		FTC		TAF		DOR								FTR			
Total use in OBR, n (%)	7 (10)	49 (68)	3 (4)	57 (79)	1 (1)	19 (26)	1 (1)	4 (6)	1 (1)	44 (61)	11 (15)	36 (50)	1 (1)	8 (11)	17 (24)	10 (14)	6 (8)

Abbreviations: 3TC=lamivudine; ABC=abacavir; AZT=zidovudine; BIC=bictegravir; DOR=doravirine; DRV=darunavir; DTG=dolutegravir; ID=identification; FPV=fosamprenavir; FTC=emtricitabine; Part.=participant; RAL=raltegravir; RPV=rilpivirine; TAF=tenofovir alafenamide; TDF=tenofovir disoproxil fumarate.
[a]Participant 31 discontinued T20 after 1 week.

References

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2. Segal-Maurer S, DeJesus E, Stellbrink HJ, et al. Capsid Inhibition with Lenacapavir in Multidrug-Resistant HIV-1 Infection. *N Engl J Med.* 2022;386(19):1793-1803.
3. Segal-Maurer S, DeJesus E, Stellbrink HJ, et al. Capsid Inhibition with Lenacapavir in Multidrug-Resistant HIV-1 Infection. [Protocol]. *N Engl J Med.* 2022;386(19):1793-1803.
4. Ogbuagu O, Segal-Maurer S, Ratanasuwan W, et al. Efficacy and Safety of Long-Acting Subcutaneous Lenacapavir in Heavily Treatment-Experienced People With Multi-Drug Resistant HIV: Week 52 Results [Oral Presentation 1585]. Paper presented at: Infectious Diseases Society of America ID Week; 19–23 October, 2022; Washington, D.C., US.
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6. Margot NA, Naik V, VanderVeen L, et al. Resistance analyses in Highly Treatment-Experienced People with HIV Treated with the Novel Capsid HIV Inhibitor Lenacapavir [Supplementary Tables]. *J Infect Dis.* 2022:1-7.

Abbreviations

ARV=antiretroviral
c/mL=copies per mL
EI=entry inhibitor
ETV=etravirine
FTR=fostemsavir
HTE=heavily treatment-experienced
IBA=ibalizumab
INSTI=integrase strand transfer inhibitor
LEN=lenacapavir
MVC=maraviroc
NNRTI=non-nucleos(t)ide reverse transcriptase inhibitor
NRTI=nucleos(t)ide reverse transcriptase inhibitor
OBR=optimized background regimen
PBO=placebo
PI=protease inhibitor
PWH=people with HIV
SUBQ=subcutaneous(ly)
T20=enfuvirtide

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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