GILEAD | Medical Information

Sunlenca® (lenacapavir) Baseline Resistance Testing

This document is in response to your request for information regarding Sunlenca® (lenacapavir [LEN]) and resistance testing at the time of treatment initiation.

This document includes content from or references to clinical practice guidelines and the inclusion of these guidelines should not be interpreted as a treatment recommendation or an endorsement of the guidelines by Gilead Sciences.

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.

Product Labeling[1]

LEN, an HIV-1 capsid inhibitor, 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.

Testing for drug-resistance prior to or when initiating LEN is not currently discussed in the Sunlenca® US prescribing information (Section 2 [Dosage and Administration]).

For unplanned missed injections, patients who miss a scheduled injection visit should be clinically reassessed, including consideration of LEN resistance testing, to ensure resumption of therapy remains appropriate.

Available Data

Baseline Resistance Testing in LEN Registrational Studies

CAPELLA: LEN in HTE PWH

CAPELLA (GS-US-200-4625) is an ongoing, phase 2/3, double-blinded, placebo-controlled clinical study designed to evaluate LEN as an add-on therapy to a failing regimen in HTE PWH with multidrug resistance.[2] Analyses of resistance at baseline included confirmation of resistance (assessed with OSS based on genotypic and phenotypic data) to ≥2 ARVs in ≥3 of the 4 main ARV classes (eg, NRTIs, NNRTIs, PIs, and INSTIs). This was done using Gag-Pro assays by Monogram Biosciences (45/72 participants) and historical resistance reports (27/72 participants) in addition to an assessment of susceptibility to entry inhibitors (eg, enfuvirtide, fostemsavir, ibalizumab, and maraviroc; 61 participants).[3]

CALIBRATE: LEN in TN PWH

CALIBRATE (GS-US-200-4334) was a phase 2, randomized, open-label, active-controlled clinical study that evaluated LEN in TN PWH. Analyses of resistance at baseline included population sequencing of HIV-1 protease, reverse transcriptase, integrase, and capsid protein genotype and phenotype through Monogram Biosciences (182 participants).[4]

Clinical Practice Guidelines

Please refer to the US Department of Health and Human Services (DHHS) Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV for further recommendations on drug-resistance testing in ARV-naïve and virologically suppressed, treatment-experienced patients: https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv.

Additionally, please refer to the International Antiviral Society-USA (IAS-USA) Guidelines for Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults: 2024 Recommendations for further recommendations on baseline resistance testing: https://pubmed.ncbi.nlm.nih.gov/39616604/.

References

1. Enclosed, Gilead Sciences Inc. SUNLENCA® (lenacapavir) tablets, for oral use. SUNLENCA® (lenacapavir) injection, for subcutaneous use. U.S. Prescribing Information. Foster City, CA.
2. Ogbuagu O, Segal-Maurer S, Ratanasuwan W, et al. Efficacy and safety of the novel capsid inhibitor lenacapavir to treat multidrug-resistant HIV: week 52 results of a phase 2/3 trial. *Lancet HIV.* 2023;10(8):e497-e505.
3. Margot N, VanderVeen L, Naik V, et al. Resistance Analysis of Long-Acting Lenacapavir in Highly Treatment-Experienced People with HIV after 26 Weeks of Treatment [Presentation]. Paper presented at: 18th European AIDS Conference (EACS); October 27-30 2021; London, UK.
4. Gupta SK, Berhe M, Crofoot G, et al. Lenacapavir administered every 26 weeks or daily in combination with oral daily antiretroviral therapy for initial treatment of HIV: a randomised, open-label, active-controlled, phase 2 trial. *Lancet HIV.* 2023;10(1):e15-e23.

Abbreviations

ARV=antiretroviral
HTE=heavily treatment experienced
INSTI=integrase strand transfer inhibitor
LEN=lenacapavir
NNRTI=non-nucleoside reverse transcriptase inhibitor
NRTI=nucleoside reverse transcriptase inhibitor
OSS=overall susceptibility score
PI=protease inhibitor
PWH=people with HIV
TN=treatment naïve

Product Label

For the full indication, important safety information, and boxed warning, 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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