GILEAD | Medical Information

Sunlenca® (lenacapavir)

Use in HIV/HCV Co-Infection

This document is in response to your request for information regarding the use of Sunlenca® (lenacapavir [LEN]) in patients co-infected with HIV-1 and HCV. Currently, there are no data to address this inquiry.

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: http://www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_pi.

Clinical Data on LEN in Participants with HIV and HCV

CAPELLA: LEN in Heavily-Treatment Experienced 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 heavily-treatment experienced people with HIV (PWH) with multidrug resistance. Participants with current HCV infection were excluded from the study.[1]

CALIBRATE: LEN in Treatment-Naïve PWH

CALIBRATE (GS-US-200-4334) was a phase 2, randomized, open-label, active-controlled clinical study that evaluated LEN in treatment-naïve PWH. Participants with current HCV infection were excluded from the study.[2]

Literature Search

A literature search was conducted in Ovid MEDLINE, BIOSIS Previews, and Embase databases for studies published between 1946 and December 9, 2024 using the search terms of Sunlenca, lenacapavir, co-infection, hepatitis C virus, and other related search terms. No relevant citations were identified.

References

1. ClinicalTrials.gov. Study to Evaluate the Safety and Efficacy of Lenacapavir in Combination With an Optimized Background Regimen in Heavily Treatment Experienced Participants Living With HIV-1 Infection With Multidrug Resistance (CAPELLA). ClinicalTrials.gov Identifier: NCT04150068. Available at: https://clinicaltrials.gov/ct2/show/NCT04150068. Accessed: 09 December 2024. Last Updated: 23 July 2024.

2. ClinicalTrials.gov. Study to Evaluate the Safety and Efficacy of Lenacapavir in Combination With Other Antiretroviral Agents in People Living With HIV (CALIBRATE). ClinicalTrials.gov Identifier: NCT04143594. Available at: https://clinicaltrials.gov/ct2/show/NCT04143594. Accessed: 09 December 2024. Last Updated: 02 October 2024.

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

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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