GILEAD | Medical Information

Livdelzi® (seladelpar)
Use in patients with Autoimmune Hepatitis or Overlap

This document is in response to your request for information regarding Livdelzi® (seladelpar [SEL]) and use in patients with autoimmune hepatitis (AIH) or AIH-PBC overlap.

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/pbc/livdelzi/livdelzi_pi.

Product Labeling[1]

SEL is indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. This indication is approved under accelerated approval based on a reduction of alkaline phosphatase (ALP).

Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Use of SEL is not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy).

Clinical Data and SEL use in Patients with AIH or Overlap

Currently there are no clinical data or guidance on the use of SEL in patients with AIH or AIH-PBC overlap. In the completed and ongoing SEL phase 3 trials RESPONSE, ENHANCE, and AFFIRM, AIH (which would also include AIH-PBC overlap) was an exclusion criteria.[2-4]

Additionally, a literature search was conducted in Ovid MEDLINE, BIOSIS Previews and Embase databases for studies published between 1946 and December 2, 2024 using search terms that included Livdelzi, seladelpar, autoimmune hepatitis, AIH-PBC overlap and related search terms. No relevant citations were found.

References

1. Enclosed. Gilead Sciences Inc. Livdelzi® (seladelpar) capsules, for oral use. US Prescribing Information. Foster City, CA.
2. Hirschfield GM, Bowlus CL, Mayo MJ, et al. A phase 3 trial of seladelpar in primary biliary cholangitis. N Engl J Med 2024;390:783-94.

3. Hirschfield GM, Shiffman ML, Gulamhusein A, et al. Seladelpar efficacy and safety at 3 months in patients with primary biliary cholangitis: ENHANCE, a phase 3, randomized, placebo-controlled study. Hepatology August 2023; 1;78(2):397-415.
4. ClinicalTrials.gov. ASSURE: An Open Label Long-Term Study to Evaluate the Safety and Tolerability of Seladelpar in Subjects With Primary Biliary Cholangitis (PBC). Available at: https://clinicaltrials.gov/study/NCT03301506.

Abbreviations

AE=adverse event
AIH=autoimmune hepatitis
CI=confidence interval
CPT=Child-Pugh-Turcotte
DC=discontinued
DCV=daclatasvir
GT=genotype
INR=international normalized ratio
ITT=intent-to-treat
LDV=ledipasvir
LTFU=lost to follow up
MELD=model for end-stage liver disease
mITT=modified intent-to-treat
PegIFN=pegylated interferon
PP=per protocol
SAE=serious adverse event
SOF=sofosbuvir
SVR=sustained virologic response
TE=treatment-experienced
TN=treatment-naïve
ULN=upper limit of normal

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Livdelzi US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/pbc/livdelzi/livdelzi_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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