GILEAD | Medical Information

Livdelzi® (seladelpar)
Use in patients with Primary Sclerosing Cholangitis

This document is in response to your request for information regarding Livdelzi® (seladelpar [SEL]) and its use in patients with primary sclerosing cholangitis (PSC).

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 Studies and SEL use in Patients with PSC

Currently there are no clinical data or guidance on the use of SEL in patients with PSC. In the completed and ongoing SEL phase 3 trials RESPONSE, ENHANCE, and ASSURE, PSC determined by the presence of diagnostic cholangiographic findings was an exclusion criteria. A phase 2, randomized, double-blind, placebo-controlled, multicenter study to evaluate the safety, tolerability, and efficacy of SEL administered for 24 weeks in adult patients with PSC (NCT04024813) was terminated early as a precautionary measure due to unexpected histological findings that were later determined to be preexisting in the nonalcoholic steatohepatitis SEL program.[2-4]

Additionally, a literature search was conducted in Ovid MEDLINE, BIOSIS Previews and Embase databases for studies published between 1946 and January 7, 2025 using search terms that included Livdelzi, seladelpar, primary sclerosing cholangitis and related search terms. No relevant citations were found.

References

1. Livdelzi Gilead Sciences Inc. LIVDELZI® (seladelpar) capsules, for oral use. US Prescribing Information. Foster City, CA Revised August. 2024.
2. 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 [Supplement]. *Hepatology.* 2023:1-37.
3. Hirschfield GM, Bowlus CL, Mayo MJ, et al. A Phase 3 Trial of Seladelpar in Primary Biliary Cholangitis.[Supplementary Appendix]. *N Engl J Med.* 2024;390(9):783-794.
4. ClinicalTrials.gov. Seladelpar in Subjects With Primary Biliary Cholangitis (PBC). Available at: https://clinicaltrials.gov/study/NCT03301506?term=NCT03301506&rank=1. Accessed: 17 May 2024. Last Updated: 15 February. 2024.

Abbreviations

ALP=alkaline phosphatase
PBC=primary biliary cholangitis
PSC=primary sclerosing cholangitis
SEL=seladelpar
UDCA=ursodeoxycholic acid

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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