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GILEAD | Medical Information

Livdelzi® (seladelpar)
Use in Patients With Autoimmune Hepatitis and Primary Biliary Cholangitis Overlap

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

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]

Indications and Usage

SEL is indicated for the treatment of PBC in combination with 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 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).

Limitations of use: Use of SEL is not recommended in patients who have or develop decompensated cirrhosis (eg, ascites, variceal bleeding, hepatic encephalopathy).

Available Data on SEL Use in Patients With AIH or AIH-PBC Overlap

Currently, no Gilead-sponsored clinical studies have been conducted to evaluate 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 criterion.[2-4]

Retrospective Cohort Study[5]

Study design and demographics

A retrospective cohort study evaluated the effectiveness and safety of SEL in various PBC subgroups, including patients with AIH-PBC overlap (N=76), using the Epic Cosmos national

electronic healthcare database. Included in the analysis were adults with PBC and ALP >1.67 × ULN. The primary endpoint was biochemical response (ALP <1.67 × ULN and ≥15% ALP reduction with normal bilirubin levels) at 6 months. Secondary endpoints included ALP normalization at 3 months and at 6 months and hepatotoxicity (ALT >3 × ULN and >5 × ULN). Baseline demographics are summarized in Table 1.

Table 1. Baseline Demographics and Disease Characteristics (Martins et al)[5]

Key Demographics and Characteristics	SEL (N=76)
Age, mean ± SD, years	62±12.2
Female, n (%)	69 (90.8)
White race,[a] n (%)	55 (72.4)
Hispanic/Latinx ethnicity, n (%)	14 (18.4)
Obesity, n (%)	40 (52. 6)
Dyslipidemia, n (%)	51 (67.1)
ALP, mean ± SD, U/L	232.2±162.6
ALP >3 × ULN, n (%)	10 (13.2)
Cirrhosis, n (%)	40 (52.6)
History of obeticholic acid use, n (%)	29 (38.2)
History of fibrates use, n (%)	10 (13.2)

[a]Additional race data were not provided.

Results

At 6 months, biochemical response was achieved by 68.8% of patients with PBC overall (n=209) and by 48.5% in the subgroup of patients with AIH-PBC (*P*=0.13). ALP normalization was achieved by 48.4% of patients with PBC and by 27.3% of patients with AIH-PBC (*P*=0.11).

Across all assessed subgroups, the proportion of patients with ALT >3 × ULN decreased from 3.5% at baseline to 1.1% at 6 months (*P*=0.043), and no patients at 6 months had ALT >5 × ULN. No cases of drug-induced liver injury were observed, and there were no renal or muscle safety concerns.

References

1. LIVDELZI®, Gilead Sciences Inc. LIVDELZI® (seladelpar) capsules, for oral use. US Prescribing Information. Foster City, CA Revised January. 2026.
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(9):783-794.
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.* 2023;78(2):397-415.
4. ClinicalTrials.gov. Seladelpar in Subjects With Primary Biliary Cholangitis (PBC) and Compensated Cirrhosis (AFFIRM). Available at: https://clinicaltrials.gov/study/NCT06051617?term=NCT06051617&rank=1. Accessed: July 2026. Last Updated: 17 July 2026.
5. Martins A, Levy C. Real-World Effectiveness and Safety of Seladelpar in Primary Biliary Cholangitis: A Nationwide Electronic Health Record-Based Study. [Poster TOP-277-YI]. European Association for the Study of the Liver (EASL) Congress; May 27-30, 2026; Barcelona, Spain.

Abbreviations

AIH=autoimmune hepatitis
ALP=alkaline phosphatase
PBC=primary biliary cholangitis
SEL=seladelpar
UDCA=ursodeoxycholic acid
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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