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Summary

ALKALINE PHOSPHATASE CHANGES WITH SELADELPAR ACROSS SUBGROUPS OF PRIMARY BILIARY CHOLANGITIS PATIENTS IN THE RESPONSE TRIAL

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In the Phase 3 RESPONSE trial, seladelpar 10 mg daily demonstrated consistent alkaline phosphatase reductions across patient subgroups in primary biliary cholangitis, including those with higher baseline disease activity and non-responders to the composite endpoint.

KEY POINTS

- Among 193 PBC patients randomised 2:1 to seladelpar versus placebo, seladelpar reduced mean ALP by 42.4% versus 4.3% with placebo at one year, with 61.7% versus 20% achieving the composite biochemical endpoint (ALP less than 1.67 times upper limit of normal, ALP decrease at least 15%, and total bilirubin at or below upper limit of normal).
- Seladelpar reduced ALP similarly across all demographic subgroups studied, including patients with cirrhosis, those diagnosed before age 50 years, and those of Hispanic or Latino ethnicity.
- In patients with baseline ALP at least 350 U/L, seladelpar produced a 44.8% decrease (216.1 U/L absolute reduction) versus 11.6% with placebo (56.4 U/L reduction), with similar percentage decreases observed across all baseline ALP quartiles.
- Among patients not meeting the composite endpoint at month 12, seladelpar still reduced ALP by 129.9 U/L versus 6.4 U/L with placebo, and prevented ALP worsening in 94.5% of seladelpar patients versus 70.8% of placebo patients.
- Adverse events occurred in similar proportions regardless of baseline ALP level (86.4% in patients with ALP below 350 U/L, 84.9% in those at or above 350 U/L), with comparable rates between seladelpar and placebo groups.

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