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Summary

ATTENUATION, NEAR RESOLUTION, AND PREVENTION OF PRURITUS IN PATIENTS WITH PRIMARY BILIARY CHOLANGITIS TREATED WITH SELADELPAR: A SECONDARY ANALYSIS OF PATTERNS OF PRURITUS CHANGE IN THE RESPONSE TRIAL

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In the Phase 3 RESPONSE trial, seladelpar 10 mg daily significantly reduced pruritus severity in PBC patients with moderate to severe itch compared to placebo over 12 months.

KEY POINTS

- Among 72 patients with baseline NRS ≥4, seladelpar reduced mean itch intensity from moderate to mild from month 3 through 12, while placebo remained moderate.
- At month 12, 46.9% of seladelpar patients achieved ≥3-point NRS decrease versus 21.7% on placebo, and 30.6% achieved ≥4-point decrease versus 8.7% on placebo.
- Near resolution of itch (NRS ≤1) occurred in 26.5% of seladelpar patients with baseline NRS ≥4 and 18.8% with NRS ≥7, compared to 0% on placebo.
- In patients without baseline itch, 0% (0/30) on seladelpar developed pruritus at month 12 versus 26.7% (4/15) on placebo.
- Adverse events occurred in similar proportions across treatment arms (88.9% with baseline NRS ≥4, 84.3% with NRS <4), and seladelpar was well tolerated regardless of baseline itch severity.

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