

LINERIXIBAT SIGNIFICANTLY IMPROVES CHOLESTATIC PRURITUS IN PRIMARY BILIARY CHOLANGITIS: RESULTS OF THE PIVOTAL PHASE 3 GLISTEN TRIAL

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Presentation

Hepatobiliary

Immunology

Mechanisms & Personalised Medicine

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GLISTEN, a Phase 3 trial in 238 PBC patients with moderate-to-severe pruritus, showed that linerixibat 40 mg twice daily significantly improved worst itch over 24 weeks compared to placebo (LS mean change -2.86 vs -2.15, adjusted difference -0.72, $p=0.001$).

KEY POINTS

- Linerixibat produced rapid pruritus improvement, demonstrating superiority over placebo as early as Week 2 (LS mean change -1.78 vs -1.07, adjusted difference -0.71, $p<0.001$).
- At Week 24, 56% of linerixibat-treated patients achieved a ≥ 3 -point reduction in pruritus versus 43% on placebo, and 21% reported absent pruritus versus 9% on placebo.
- Linerixibat significantly improved pruritus-related sleep interference over 24 weeks versus placebo (LS mean change -2.77 vs -2.24, adjusted difference -0.53, $p=0.024$).
- Diarrhoea was the most common adverse event, occurring in 61% of linerixibat-treated patients versus 18% on placebo, but only 4% discontinued treatment due to diarrhoea.
- The study enrolled 238 patients, 95% female, with baseline mean itch severity 7.34, of whom 47% were receiving stable antipruritic therapy and 52% had alkaline phosphatase <1.67 times upper limit of normal.

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