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Summary

ELAFIBRANOR TREATMENT RESULTS IN RAPID REDUCTIONS IN BIOCHEMICAL MARKERS AND SYMPTOM BURDEN IN REAL-WORLD PRACTICE: INTERIM RESULTS FROM THE PROSPECTIVE, NON-INTERVENTIONAL ELFINITY PHASE IV GLOBAL STUDY IN PATIENTS WITH PRIMARY BILIARY CHOLANGITIS

Michael Trauner

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ELFINITY, a global real-world study of elafibranor in PBC second-line treatment, showed at 3 months that 55% of patients achieved biochemical response (ALP <1.67× ULN with ≥15% reduction and bilirubin ≤ULN) and the drug was well tolerated with no serious adverse events.

KEY POINTS

- At Month 3, 28/51 patients (55%) achieved biochemical response, and 11/49 (22%) with elevated baseline ALP achieved ALP normalisation; mean ALP decreased by 0.7× ULN.
- Among patients with ALP between 1 and 1.67× ULN at baseline, 8/20 (40%) achieved ALP normalisation at Month 3.
- Of OCA-experienced patients, 7 improved and 1 worsened by one ALP category at Month 3, while 8 maintained the same category.
- Among patients with moderate-to-severe symptoms at baseline, 57% showed clinically meaningful improvement in PBC-40 Fatigue and 100% in both PBC-40 Itch and WI NRS pruritus scores at Month 3.
- Safety was favorable: 26/53 patients (49%) had treatment-emergent adverse events, none serious or severe; most common were fatigue (n=6), headache (n=5), diarrhoea (n=5), and nausea (n=5); 6 patients discontinued by Month 3.

– ELFINITY is an ongoing prospective phase IV study enrolling approximately 424 patients globally to receive elafibranor 80 mg/day with follow-up for up to 5 years; this analysis represents 53 treated patients as of October 2025.

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