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Summary

PEGOZAFERMIN DEMONSTRATED ROBUST HISTOLOGICAL IMPROVEMENT AND BENEFIT IN HEPATIC AND METABOLIC BIOMARKERS: RESULTS FROM A 48-WEEK MULTI-CENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE 2B TRIAL (ENLIVEN)

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UEG Week Berlin 2025 | Presentation

Hepatobiliary

October 7, 2025

Pegozafermin, an FGF21 analog, demonstrated statistically significant fibrosis regression and MASH resolution at 24 weeks in patients with F2/F3 fibrosis in the Phase 2b ENLIVEN trial.

KEY POINTS

- Treatment with pegozafermin 30mg weekly or 44mg every two weeks achieved both primary histological endpoints: one-stage fibrosis improvement without worsening of MASH and MASH resolution without worsening of fibrosis, compared to placebo.
- Pegozafermin is the first therapy to achieve fibrosis regression and MASH resolution with an every-two-week dosing regimen.
- Non-invasive tests at weeks 24 and 48 showed robust and sustained reductions in liver fat content by MRI-PDFF, biomarkers of fibrosis including VCTE, ELF, and PRO-C3, and liver injury markers ALT and AST.
- Metabolic parameters including lipids and HbA1c improved at both 24 and 48 weeks.
- Pegozafermin was generally safe and well tolerated, with the most common adverse events being mild to moderate nausea and diarrhea; no deaths occurred and six patients discontinued early for treatment-emergent adverse events including one drug-related serious adverse event.
- Phase 3 studies ENLIGHTEN-Fibrosis in noncirrhotic patients and ENLIGHTEN-cirrhosis in cirrhotic patients are currently underway.

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