

ANALYSES OF FIBROSIS BIOMARKERS PRO-C3 AND ELF IN RESMETIROM TREATED PATIENTS FROM MAESTRO-NASH, A 52 WEEK NASH/MASH SERIAL LIVER BIOPSY STUDY

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UEG Week Vienna 2024

Presentation

Hepatobiliary

October 14, 2024

In the MAESTRO-NASH Phase 3 trial, resmetirom 80 mg and 100 mg significantly reduced the fibrosis biomarker PRO-C3 at week 52 compared with placebo, with the largest reductions observed in patients with F3 fibrosis.

KEY POINTS

- Resmetirom 100 mg reduced PRO-C3 by -23.05 ng/ml and 80 mg by -17.93 ng/ml versus -0.19 ng/ml for placebo at week 52, with mean differences of -22.1 ($p < 0.0001$) and -16.9 ($p = 0.0011$) versus placebo, respectively.
- In F3 patients, PRO-C3 reductions were larger: -27.42 for 100 mg and -22.42 for 80 mg versus -0.50 for placebo, indicating the assay was more sensitive in advanced fibrosis.
- Two PRO-C3 ELISA assays (GEN1 and GEN2) were positively correlated ($r = 0.78$, $p < 0.0001$), validating the GEN2 assay for measuring PRO-C3 levels.
- Week 52 changes in P3NP correlated strongly with PRO-C3 changes ($r = 0.52-0.56$), while ELF score changes showed weaker correlation ($r = 0.48-0.49$).
- MAESTRO-NASH is an ongoing 54-month trial in 966 patients with biopsy-confirmed NASH randomized 1:1:1 to resmetirom 80 mg, 100 mg, or placebo, which met dual primary histological endpoints at week 52.

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