

Abstract O23 Figure 1

hypertension. The difference in all-cause and liver-related mortality suggests that this survival benefit may not be entirely liver related.

## REFERENCES

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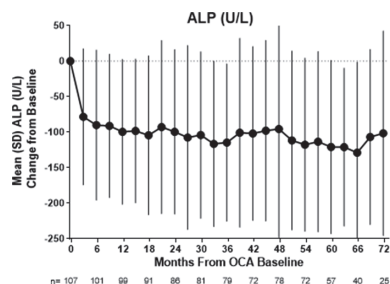
O24

#### DURABILITY OF OBETICHOLIC ACID RESPONSE IN PBC PATIENTS WHO DID NOT ACHIEVE POISE TRIAL CRITERIA

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**Introduction** In clinical studies and in clinical practice, response to primary biliary cholangitis (PBC) treatment has been assessed using dichotomous biochemical response criteria. Although achieving these criteria may be associated with improved clinical outcomes, the benefit in patients (pts) with an incomplete response to treatment may be underestimated.



This analysis assessed the extent and durability of obeticholic acid (OCA) response in pts with PBC not achieving the dichotomous primary endpoint in the phase 3 POISE study through 72 months of OCA treatment.

**Methods** Key inclusion criteria included PBC diagnosis, alkaline phosphatase (ALP)  $\geq 1.67 \times$  upper limit of normal (ULN) and/or total bilirubin  $> ULN$  to  $< 2 \times ULN$ , and on a stable dose of—or intolerant of—ursodeoxycholic acid (UDCA). During the 12-month double-blind (DB) phase, 216 pts were randomised to daily placebo, OCA 5–10 mg, or OCA 10 mg. This analysis pooled DB placebo (OCA baseline [BL]) was open-label extension [OLE] day 0) and DB OCA pts to evaluate the efficacy and safety of up to 72 months of OCA treatment. Pts who achieved the POISE primary endpoint (ALP  $< 1.67 \times ULN$ , with a  $\geq 15\%$  reduction from BL, and total bilirubin  $\leq ULN$ ) 12 months from OCA BL were excluded. Values shown are mean (SD) unless otherwise specified. P values were based on paired t-tests.

**Results** Of the 193 pts enrolled in the OLE, 107 (55%) did not achieve the POISE criteria after 12 months of OCA treatment. Pts were 93% female, 91% Caucasian, 56 (10) years old at BL, and 91% received UDCA (15 [4] mg/kg/day). At BL, ALP was 356 (138) U/L and total bilirubin was 13 (8)  $\mu\text{mol/L}$  ( $> ULN$  in 18 pts [17%]). Despite not achieving the POISE criteria after 12 months of OCA, a significant and durable reduction was observed in ALP ( $p < 0.01$  at all time points) through 72 months of treatment (figure 1). Total bilirubin levels remained stable and near BL values within the normal range throughout the duration of treatment. Throughout the 6-year study period, the most common adverse events were pruritus (92 pts [86%]) and fatigue (33 pts [31%]), consistent with previous reports from POISE and expected PBC symptoms.

**Conclusions** Despite not achieving the POISE primary endpoint, these pts showed significant and sustained biochemical improvements.

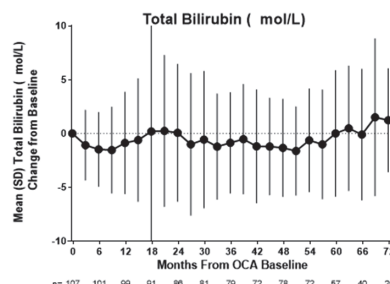
O25

#### ALCOHOL RELATED LIVER DISEASE: DELAYED DIAGNOSIS AND MISSED OPPORTUNITIES FOR INTERVENTION

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**Introduction** Death from alcohol related liver disease (ARLD) is preventable and increasing. Effective identification and brief



Abstract O24 Figure 1 Change from baseline in ALP and total bilirubin through 72 months of OCA treatment