

Abstract P212 Figure 1 Comparison for bilirubin, IgG positivity and years until resolution of liver enzymes between the AIH and DILI groups

Conclusions ALT/ALP ratio, Bilirubin >100, and high MELD scores are useful in differentiating diagnosis of acute AIH vs. DILI. Furthermore, the higher ALT/ALP ratio indicates AIH is predominately a hepatitic process, whereas DILI more commonly has a mixed hepatitis/biliary profile.

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OBETICHOLIC ACID IMPROVES HEPATIC FIBROINFLAMMATION ASSESSED BY MULTIPARAMETRIC MRI: INTERIM RESULTS OF THE REGENERATE TRIAL

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Introduction A Month 18 interim analysis of REGENERATE showed that treatment with obeticholic acid (OCA) improved fibrosis and steatohepatitis based on liver histology in patients with nonalcoholic steatohepatitis (NASH). However, liver biopsy has several limitations and development of noninvasive

tools for diagnosis and monitoring of NASH is warranted. Here, we evaluate the effects of OCA on multiparametric, MRI-derived, iron-corrected T1 (cT1) mapping.

Methods Multiparametric MRI by LiverMultiScan was performed in a subset of REGENERATE patients with fibrosis stage 2–3 (N=20) randomised 1:1:1 to placebo (n=7), OCA 10 mg (n=6), or OCA 25 mg (n=7). Changes in cT1 and liver fat content were evaluated after 18 months of treatment.

Results At baseline, mean (SD) cT1 was similar across all groups (856.7 [106.8] ms; 943.2 [116.11] ms; and 882.1 [94.75] ms in placebo, OCA 10-mg, and OCA 25-mg groups, respectively); elevated values reflect definite steatohepatitis and significant fibrosis. After 18 months of treatment, a dose-dependent reduction in cT1 was observed with a mean change from baseline of -91.7 ms in the OCA 25-mg group and -59.6 ms in the OCA 10-mg group, compared to -1.4 ms in the placebo group. Mean liver fat content at baseline was 16.29% (placebo), 19.27% (OCA 10 mg), and 15.3% (OCA 25 mg). Modest reduction (-7.9%) in fat content was noted with OCA 25-mg as early as 6 months and was generally sustained through Month 18 (figure 1).

Conclusions Treatment with OCA resulted in dose-dependent improvements in cT1 and liver fat content by multiparametric MRI, which may be consistent with histologic improvements in steatohepatitis and fibrosis, and in serum-based noninvasive markers of steatohepatitis and fibrosis (Anstee 2019). The REGENERATE study remains ongoing and will continue through clinical outcomes for verification and description of clinical benefit.

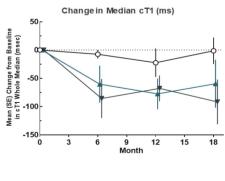
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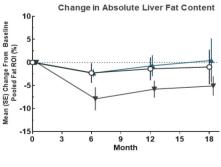
PREDICTED RISK OF END STAGE LIVER DISEASE UTILIZING THE UK-PBC RISK SCORE IN PBC PATIENTS

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Introduction The UK-PBC Study group developed and validated a long-term prognostic model of primary biliary cholangitis (PBC) based on data from ~3000 patients (pts) with PBC. The model uses albumin, platelets, alanine





O- Placebo ★ OCA 10 mg ▼ OCA 25 mg

Abstract P213 Figure 1 Fibroinflammatory disease and fat content by multiparametric MRI

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