

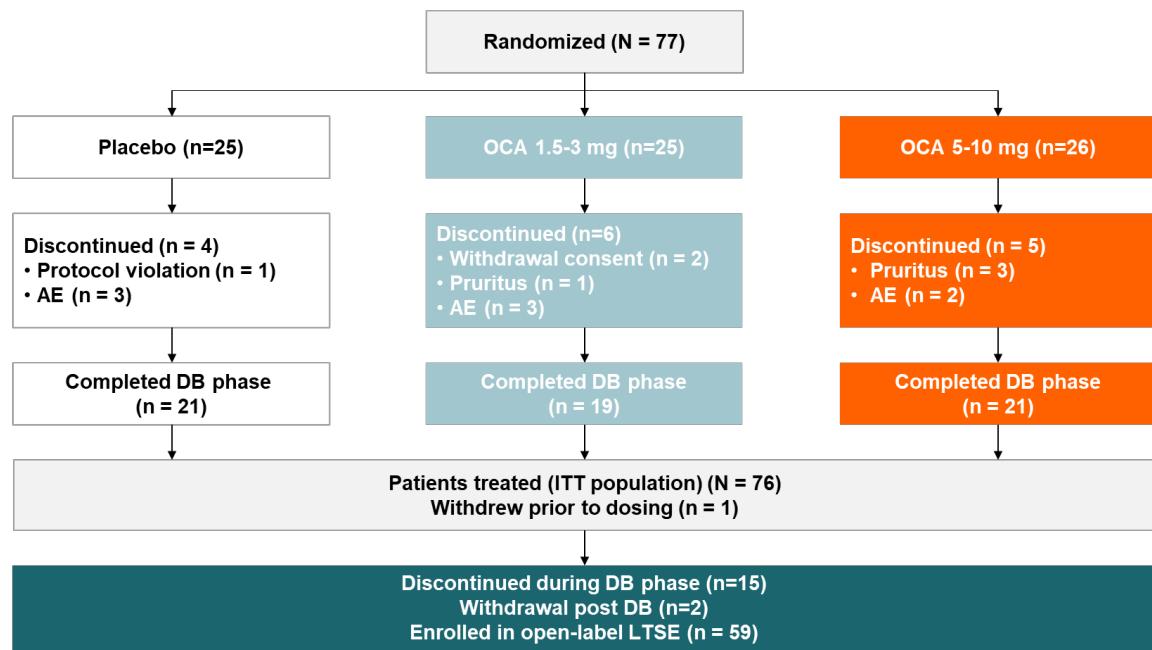
# **A randomized, placebo-controlled, phase II study of obeticholic acid for primary sclerosing cholangitis**

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on behalf of the AESOP Study Investigators

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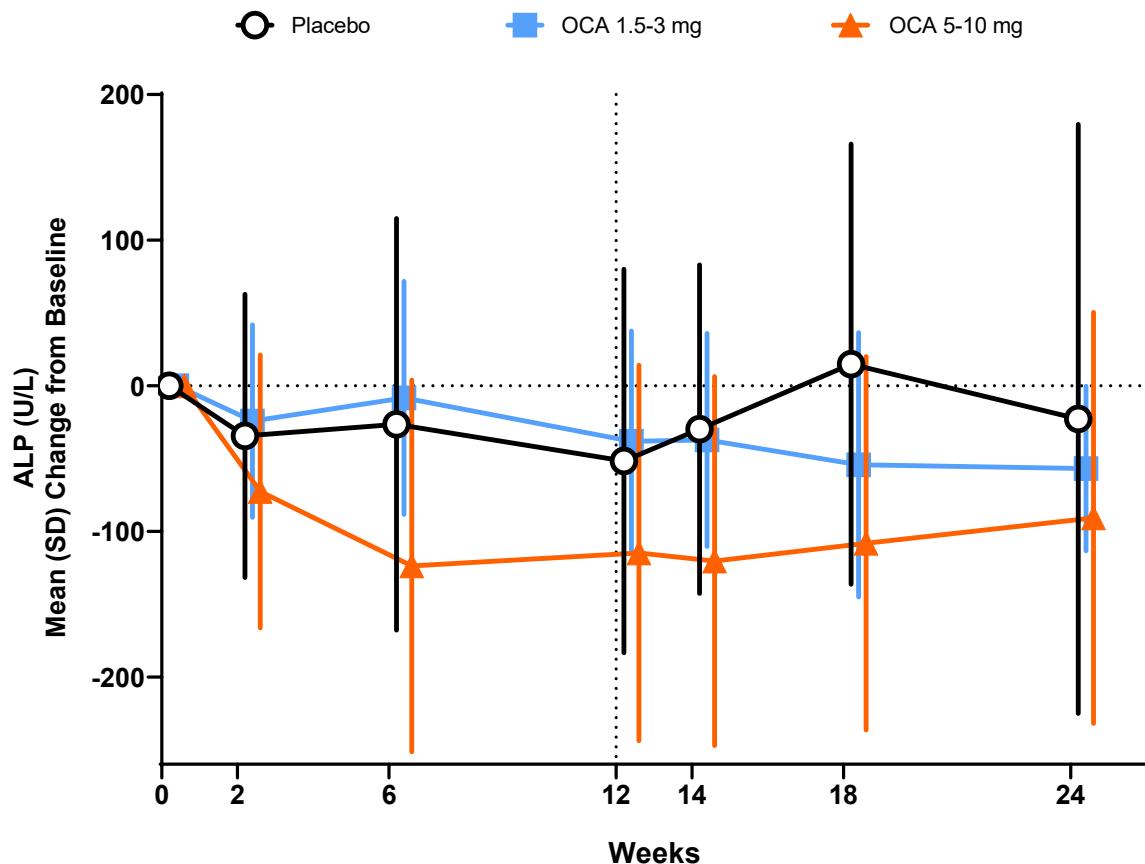
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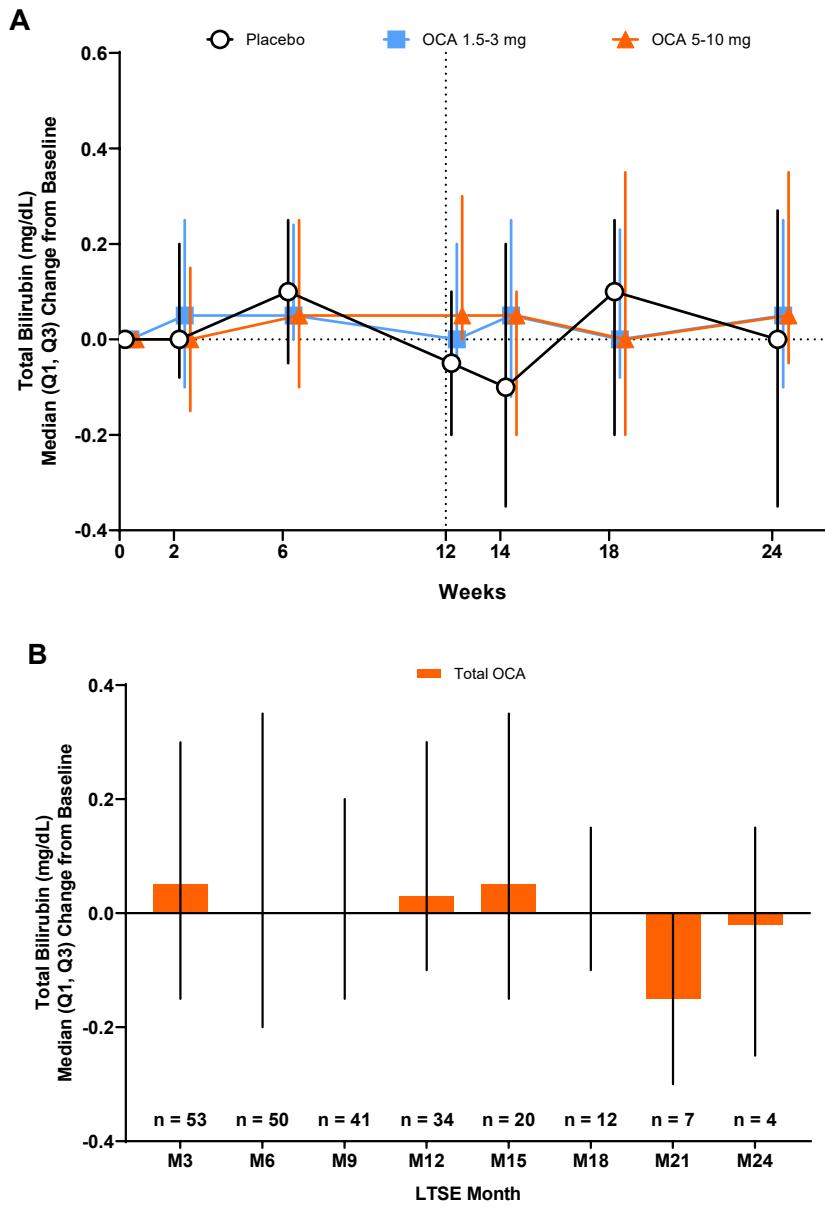
**Fig. S1. Patient disposition.**

AE, adverse event; DB, double-blind; ITT, intent-to-treat; LTSE, long-term safety extension; OCA, obeticholic acid.



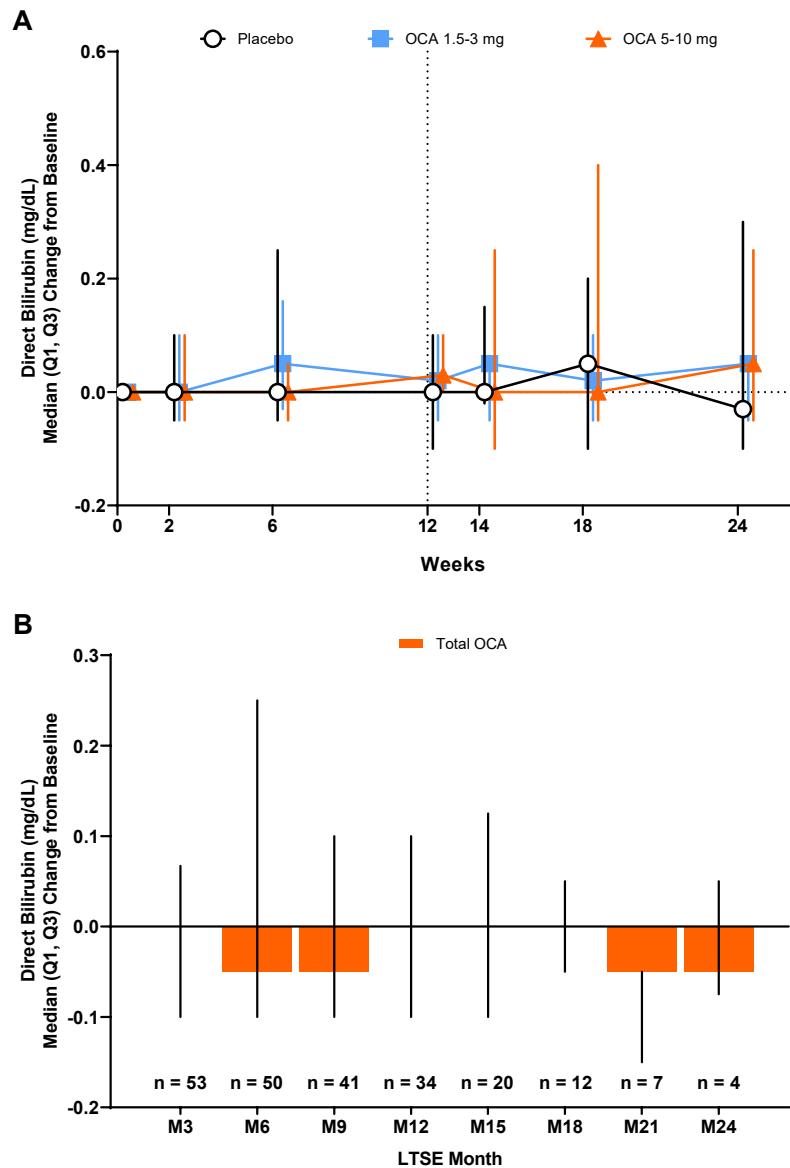
**Fig. S2. Mean change from baseline in ALP over time by original treatment group.**

Mean (SD) change from baseline in serum ALP in the DB phase are plotted by original treatment group (safety population) for patients who entered the LTSE. ALP, alkaline phosphatase; DB, double-blind; LTSE, long-term safety extension; OCA, obeticholic acid; SD, standard deviation.



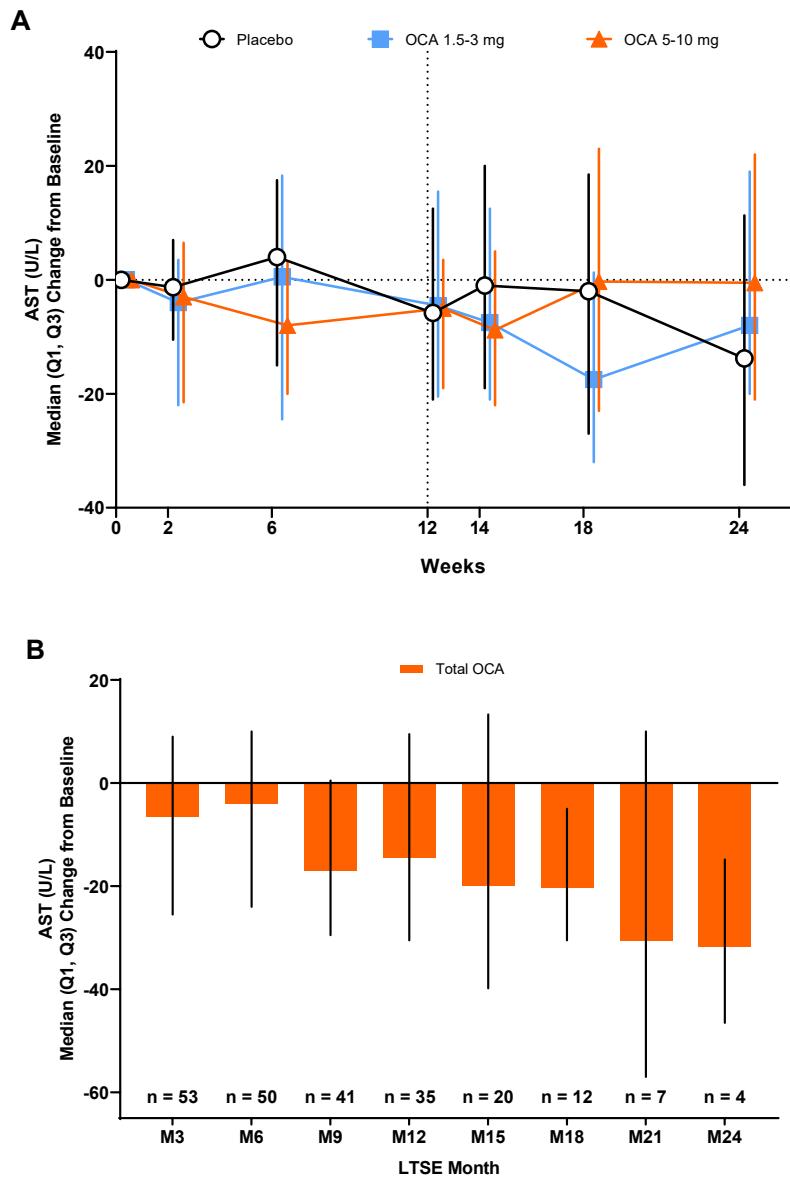
**Fig. S3. Median change from baseline in total bilirubin over time by treatment group.**

(A) Median (Q1, Q3) change from baseline in serum total bilirubin in the DB phase (safety population). (B) Median (Q1, Q3) change from baseline in serum total bilirubin in the LTSE (pooled data). DB, double-blind; LTSE, long-term safety extension; OCA, obeticholic acid; Q, quartile.



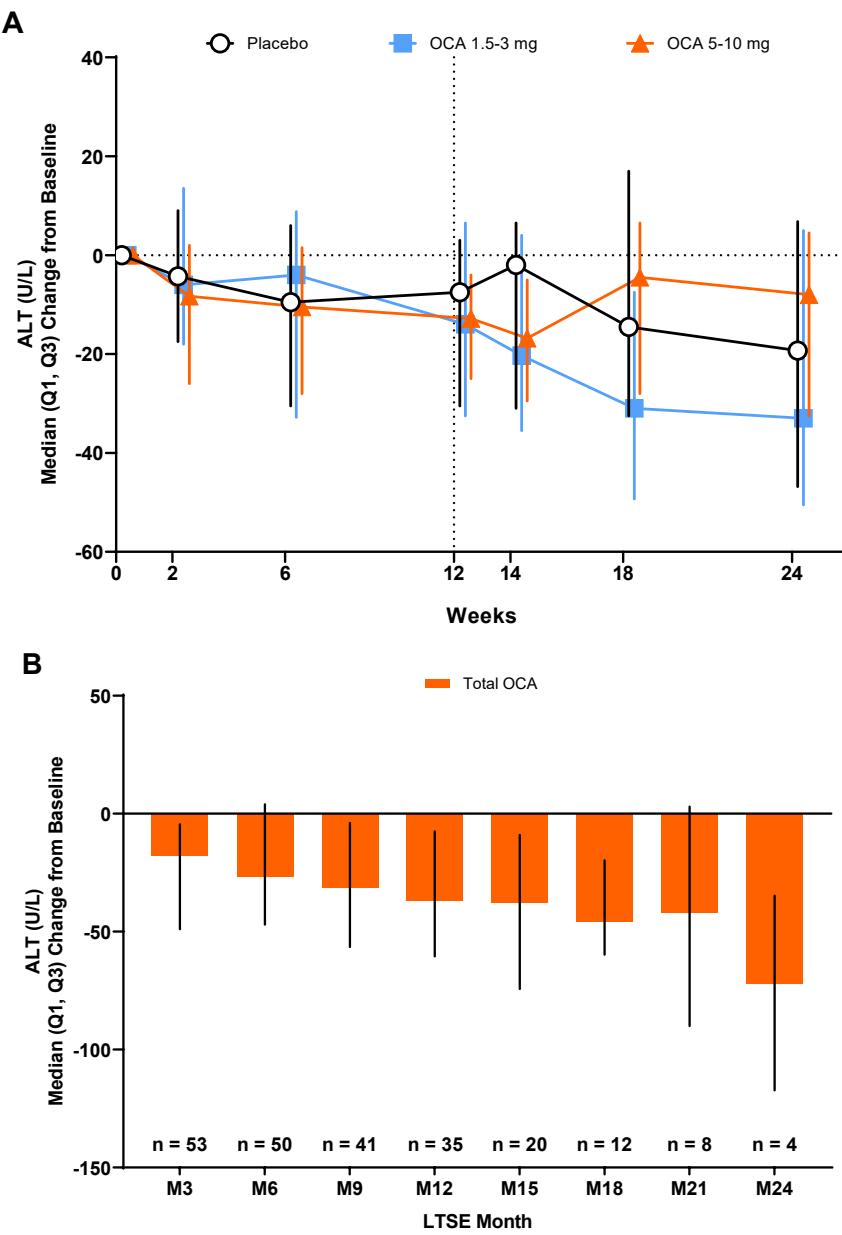
**Fig. S4. Median change from baseline in direct bilirubin over time by treatment group.**

**(A)** Median (Q1, Q3) change from baseline in serum direct bilirubin in the DB phase (safety population). **(B)** Median (Q1, Q3) change from baseline in serum direct bilirubin in the LTSE (pooled data). DB, double-blind; LTSE, long-term safety extension; OCA, obeticholic acid; Q, quartile.



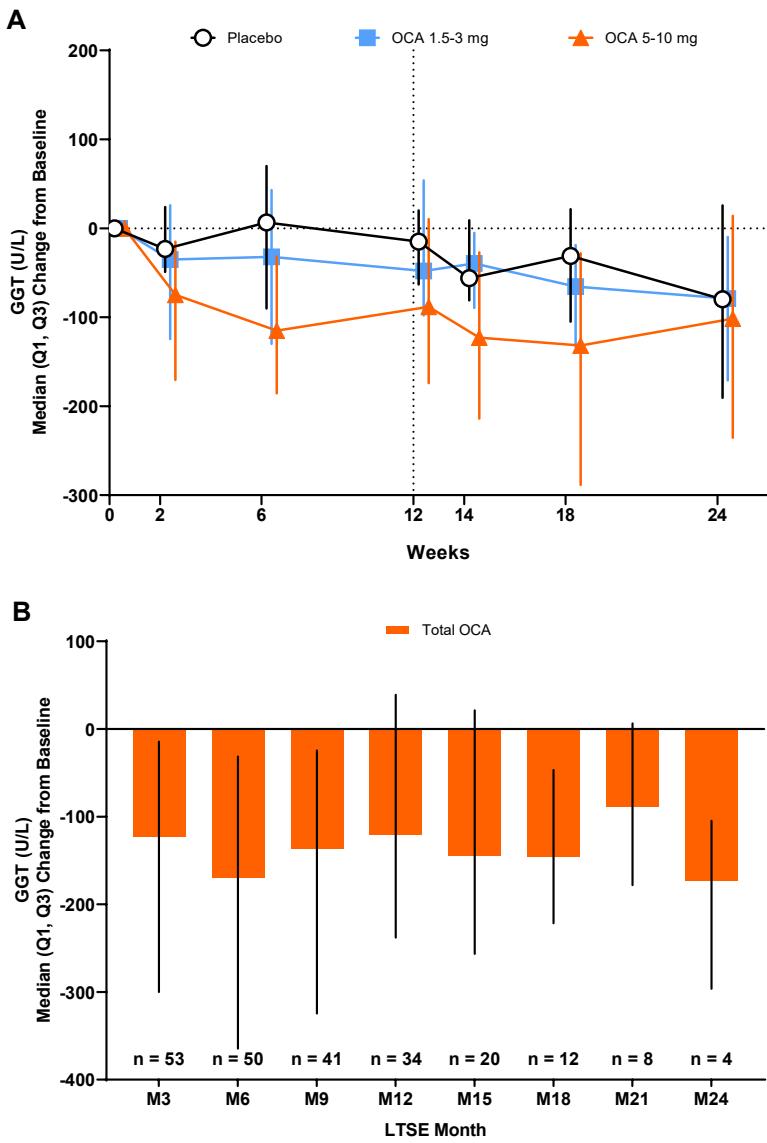
**Fig. S5. Median change from baseline in AST over time by treatment group.**

(A) Median (Q1, Q3) change from baseline in serum AST in the DB phase (safety population). (B) Median (Q1, Q3) change from baseline in serum AST in the LTSE (pooled data). AST, aspartate aminotransferase; DB, double-blind; LTSE, long-term safety extension; OCA, obeticholic acid; Q, quartile.



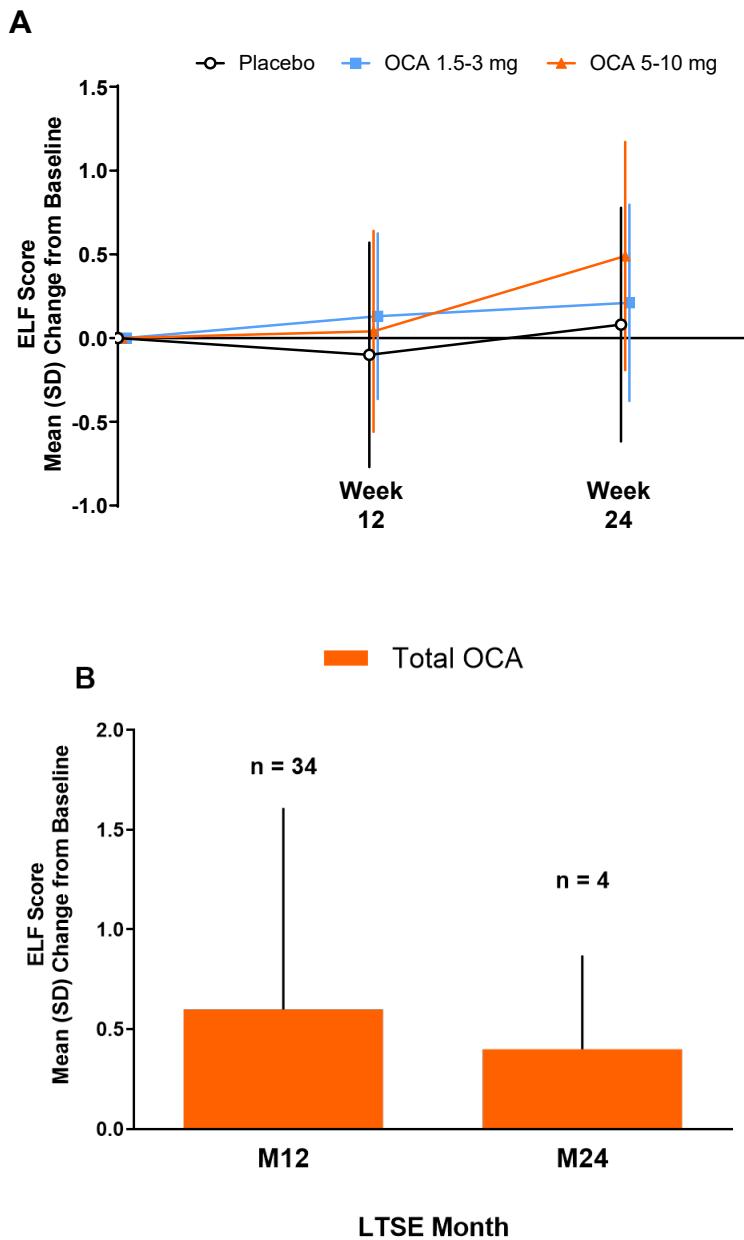
**Fig. S6. Median change from baseline in ALT over time by treatment group.**

**(A)** Median (Q1, Q3) change from baseline in serum ALT in the DB phase (safety population). **(B)** Median (Q1, Q3) change from baseline in serum ALT in the LTSE (pooled data). ALT, alanine aminotransferase; DB, double-blind; LTSE, long-term safety extension; OCA, obeticholic acid; Q, quartile.



**Fig. S7. Median change from baseline in GGT over time by treatment group.**

**(A)** Median (Q1, Q3) change from baseline in serum GGT in the DB phase (safety population). **(B)** Median (Q1, Q3) change from baseline in serum GGT in the LTSE (pooled data). DB, double-blind; GGT, gamma-glutamyl transferase; LTSE, long-term safety extension; OCA, obeticholic acid, Q, quartile.



**Fig. S8. Mean change from baseline in ELF over time by treatment group.**

(A) Mean (SD) change from baseline in ELF score in the DB phase (ITT population). (B) Mean (SD) change from baseline in ELF score in the LTSE (pooled data). DB, double-blind; ELF™, Enhanced Liver Fibrosis; ITT, intent-to-treat; LTSE, long-term safety extension; OCA, obeticholic acid; SD, standard deviation.