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# Zydus receives US FDA approval to initiate Phase 2(b)/3 on liver disease

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**The positive results from the Phase 2(a) Clinical Trial Evaluating Saroglitazar Mg in patients with NASH were published in the Journal of Hepatology**

Zydus has received permission from the US FDA to initiate the Phase 2(b)/3 Prospective, multi-centre, randomised, double-blind, placebo-controlled adaptive clinical trial to evaluate the efficacy and safety of Saroglitazar Magnesium in Subjects With Primary Biliary Cholangitis (PBC). PBC is a severe liver disease leading to cirrhosis of the liver, liver failure, and possibly death.

The EPICS-IIITM trial will randomise 192 subjects in a 1:1:1 ratio to Saroglitazar 1 mg, Saroglitazar 2 mg or Placebo and will study the Saroglitazar Magnesium (1 or 2 mg) relative to Placebo based on the composite endpoints of Alkaline Phosphatase (ALP), total bilirubin, liver stiffness measurement (LSM) by FibroScan, liver enzyme parameters (ALT, AST, GGT, total bilirubin, and albumin), lipid parameters (TG, LDL-C, HDL-C, VLDL-C, total cholesterol, and non-HDL-C), health-related quality of life using PBC 40 questionnaire (a patient-derived, disease-specific quality of life measure developed and validated for use in PBC) and other outcome measures over 52 weeks.

The EPICS-IIITM Phase 2(b)/3 trial will be led by Prof Naga Chalasani, Interim Chair, Department of Medicine, Indiana University School of Medicine as Principal Investigator.

The Phase 2(a) EPICS trials results published in the *Journal of Hepatology* has demonstrated that Saroglitazar holds immense potential based on its safety and efficacy profile.