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Zydus initiates phase II trial for NAFLD drug

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Phase 2 clinical trial of Saroglitazar Magnesium in NAFLD with PCOS

Zydus Cadila, an innovation-driven, global pharmaceutical company, announced that it has initiated a Phase 2 clinical trial for evaluating the effect of Saroglitazar Mg in the treatment of NonAlcoholic Fatty Liver Disease (NAFLD) in women with polycystic ovary syndrome (PCOS). The EVIDENCES VII trial is currently recruiting patients across several clinical sites in the United States of America and Mexico.

Research suggests that in women with polycystic ovary syndrome (PCOS), the risk for NonAlcoholic Fatty Liver Disease is increased. PCOS affects fertility and also significantly increases metabolic complications.

Saroglitazar Magnesium is an investigational molecule in USA, undergoing clinical evaluation for treatment of liver diseases like NAFLD with PCOS, Non-Alcoholic SteatoHepatitis (NASH) and Primary Biliary Cholangitis (PBC).

Speaking on the development, Mr. Pankaj R. Patel, Chairman, Zydus Group said, “We are happy with the progress of our investigational molecule, Saroglitazar Mg in the study for addressing several unmet healthcare needs including Non-Alcoholic SteatoHepatitis and NAFLD. Our research programme aims at bringing innovative therapies that make a difference to human lives in keeping with our mission to create healthier communities.”

The trial will evaluate the change in hepatic fat content from baseline following 24 weeks of treatment as measured by MRI-PDFF in patients treated with Saroglitazar Magnesium as compared to placebo as the primary endpoint. The secondary endpoints of the trial also include measurements of liver enzymes, insulin resistance, liver fibrosis, liver stiffness, BMI, waist circumference, MRIderived measures of total liver fat index, MRI-derived measures of total liver volume, lipid and lipoprotein levels, SHBG level, ovarian function, free androgen index and pharmacokinetic parameters.