

## **Zydus announces patient enrollment in EVIDENCES VII Phase 2 clinical trial of Saroglitazar Magnesium in NAFLD with PCOS**

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Ahmedabad, India, 21 August 2019

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 Non-Alcoholic 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. [ClinicalTrials.gov Identifier: NCT03617263]

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

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.”

There is a high prevalence of PCOS in the general population affecting 1 in 10 women of childbearing age, causing infrequent or prolonged menstrual periods or excess male hormone (androgen) levels. Polycystic ovary syndrome (PCOS) is caused due to factors like obesity or insulin resistance, affecting liver function and leading to Non-Alcoholic Fatty Liver Disease (NAFLD). There are currently no treatments approved by the U.S. Food and Drug Administration (USFDA) for treatment of NAFLD or NASH.

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, MRI-derived 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.

## **About Saroglitazar Magnesium**

Saroglitazar Magnesium is an investigational molecule in USA, undergoing clinical evaluation for treatment of liver diseases like NAFLD with polycystic ovary syndrome (PCOS), Non-Alcoholic SteatoHepatitis (NASH) and Primary Biliary Cholangitis (PBC). Nonclinical studies have demonstrated that Saroglitazar, because of its unique mechanism of engaging PPAR alpha and PPAR gamma, favorably affects all components of NASH including steatosis, ballooning, inflammation and fibrosis.

## **About Zydus**

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies, including small molecule drugs, biologic therapeutics and vaccines. The group employs over 23,000 people worldwide, including 1400 scientists engaged in R & D, and is dedicated to creating healthier communities globally. [www.zyduscadila.com](http://www.zyduscadila.com)