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DCGI approves Zydus Cadila's Saroglitazar Mg for NAFLD treatment

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Saroglitazar Mg, approved by DCGI becomes the first medicine for the treatment of NonAlcoholic Fatty LiverDisease (NAFLD)

Zydus Cadila has announced that the Drug Controller General of India (DCGI) has approved its New Drug Application (NDA) for Saroglitazar Mg for the treatment of non-alcoholic fatty liver disease (NAFLD) in India.

Speaking about the development, Pankaj Patel, Chairman, Zydus Group said, "With Saroglitazar Mg, we have been able to successfully offer an innovative medicine for dealing with chronic liver diseases like NAFLD and NASH and helping patients in leading healthier lives."

Saroglitazar Mg was launched in India in September 2013, for the treatment of diabetic dyslipidemia and hypertriglyceridemia in patients with type-2 diabetes not controlled by statins alone. In January this year, Saroglitazar Mg received an approval for the treatment of Type 2 Diabetes Mellitus. In March 2020, Saroglitazar Mg had received approval for the treatment of NASH.

Zydus achieved positive results in the EVIDENCES III trial (CTRI/2015/10/006236), a Phase 3 liver biopsy trial of Saroglitazar Mg 4 mg versus Placebo in Indian patients with NASH. The trial evaluated histological improvement of NASH using liver biopsy at the end of 52 weeks and successfully met primary and secondary endpoints. Saroglitazar Mg 4 mg demonstrated a significant reduction in liver fat, liver enzymes and disease activity.

Additionally, 15 investigator initiated clinical studies of Saroglitazar Mg have been presented and published in leading scientific journals and conferences. Saroglitazar Mg is a prescription drug approved in India, and should be taken under guidance of a registered medical practitioner.