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Zydus brings world's first drug for treating NASH

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NASH is a progressive disease of the liver

Zydus Cadila, an innovation-driven global pharmaceutical company has announced that the Drug Controller General of India (DCGI) has approved its New Drug Application (NDA) for Saroglitazar for the treatment of Non-Cirrhotic Non-Alcoholic SteatoHepatitis (NASH) in India. The drug will enter the Indian market within three months. The drug will also be launched in Mexico soon.

NASH is a progressive disease of the liver, which starts with fat accumulation in the liver known as Non-Alcoholic Fatty Liver Disease (NAFLD). This condition could progress to cirrhosis and liver failure. It is a large unmet medical need as there is currently no approved drug for the treatment of NASH anywhere in the world, a disease that is highly prevalent with 10% to 30% of the global population being affected by it. The prevalence of NASH in India is estimated to be nearly 25% of the population. NASH ranks as one of the major causes of cirrhosis, behind hepatitis C and alcoholic liver disease. Liver transplantation is the only option for managing advanced cirrhosis with liver failure.

Speaking about the development, Pankaj Patel, Chairman, Zydus Group mentioned, “We are happy that our efforts to discover and develop a novel drug for patients living with NASH, an unmet healthcare need globally have been successful. Saroglitazar will provide hope and new lease of life for millions of patients in India suffering from NASH.”

Saroglitazar 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 received an approval for the treatment of Type 2 Diabetes Mellitus. In the last seven years, over a million patients have benefitted from this drug.

Saroglitazar is uniquely poised with its dual PPAR alpha and gamma properties – reducing the comorbidities (dyslipidemia, hypertriglyceridemia, diabetes mellitus) and causing NASH resolution.