Zydus Cadila scores first ever NASH approval, in India

Drug has already been approved for diabetes related conditions

Zydus Cadila has become the first pharma company in the world to win approval for a non-alcoholic steatohepatitis (NASH) drug, after getting a green light from the Drug Controller General of India (DCGI).

The drug – saroglitazar – has been available for use in the treatment of diabetic dyslipidemia and hypertriglyceridemia in patients with uncontrolled type 2 diabetes since 2013.

Zydus also scored approval for the drug as a treatment for type 2 diabetes in January this year, with this most recent approval in **NASH** adding to the resounding success of sargolitazar for the Indian pharma company.

According to Zydus, around 25% of the population in India are estimated to have NASH, which is the most common cause of cirrhosis – following hepatitis C and alcoholic liver disease.

That makes it a significant market – in fact, according to GlobalData, the global market for NASH could be worth up to $25bn over the next few years.

The NASH market is also largely untapped, thanks to many failed attempts in the area, including Gilead's **selonsertib**, Novartis/Conatus' emricasan and Cymabay's seladelpar.

NASH is characterised by a build-up of fat that can lead to fibrosis, cirrhosis and sometimes the need for a liver transplant, in severe cases.

The approval of saroglitazar was based on results from the phase 3 EVIDENCES II trial, which evaluated histological improvement of NASH using liver biopsy at the end of 52 weeks.

The drug met both primary and secondary endpoints, demonstrating a significant reduction in liver fat, liver enzymes and disease activity compared to placebo.

"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," said Pankaj Patel (pictured left), chairman of Zydus Group.

“Saroglitazar will provide hope and new lease of life for millions of patients in India suffering from NASH,” he added.

Another potential treatment for NASH – from **Intercept** – is currently under review with the US Food and Drug Administration (FDA).

However, in January the FDA pushed back the target action date for the drug to 26 June, three months after the originally scheduled March date.

“This typical three-month extension provides the time needed to accommodate the advisory committee meeting and for the FDA to complete its review of the company’s [new drug application], including additional information provided in response to FDA requests,” Intercept wrote in the filing at the time.