



Torrent and Zydus sign licensing agreement for co-marketing Saroglitazar Mg, a critical treatment for chronic liver diseases in India

- *Saroglitazar Magnesium, approved by the DCGI, is an innovative drug from Zydus to treat patients with chronic liver diseases such as, Non-Alcoholic Steato Hepatitis (NASH) and Non-Alcoholic Fatty Liver Disease (NAFLD).*
- *Torrent will market the drug under the brand name VORXAR®.*
- *Zydus continues to market the drug under the brand names Lipaglyn® and Bilypsa®.*

Ahmedabad, November 10, 2023

Torrent Pharmaceuticals Limited (“Torrent”), a specialty focussed global pharmaceutical company, and Zydus Lifesciences Limited (including its subsidiaries/affiliates hereafter referred to as “Zydus”) a discovery-driven, global lifesciences company, today announced that they have entered into a licensing and supply agreement to co-market Saroglitazar Mg for the treatment of Non-Alcoholic Steato Hepatitis (NASH) and Non-Alcoholic Fatty Liver Disease (NAFLD) in India. As the only approved drug for NASH and NAFLD in the country, Saroglitazar Magnesium is likely to play a key role in managing and mitigating these progressive and prevalent liver disorders.

With a once daily, 4mg dose regimen, Saroglitazar Mg enables better compliance, reduces pill burden and offers greater convenience for patients.

Under the terms of this agreement, Torrent will have semi-exclusive rights to co-market the product in India under the brand name VORXAR®. Zydus launched the drug under the brand names Lipaglyn® and Bilypsa® and will continue to market them. Torrent will pay Zydus upfront licensing fees and milestone payments based on the achievement of pre-defined milestones.

Saroglitazar Mg, is an innovative drug from Zydus approved by the DCGI to treat chronic liver diseases such as, Non-Alcoholic Steato Hepatitis (NASH) and Non-Alcoholic Fatty Liver Disease (NAFLD). India is the first country to have a drug approved for these unmet medical needs. Currently, there is no approved drug for the treatment of NASH and NAFLD anywhere else in the world.

Speaking on the development, Managing Director, Zydus Lifesciences Ltd., Dr. Sharvil Patel said, “This association with Torrent is testament to our long-term vision of expanding the reach of our drug. Our vision is to help empower patients with life changing discoveries powered by

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innovation. Saroglitazar Mg is one of the critical treatments for patients with NASH and NAFLD and bridges an unmet healthcare need.”

Aman Mehta, Director, Torrent Pharmaceuticals Ltd. said, “In NASH and NAFLD, disease areas with high prevalence and limited therapeutic options that are backed by clinical evidence, Saroglitazar Magnesium represents a significant advancement. We are delighted to partner with Zydus and add Saroglitazar Magnesium, under brand name Vorxar[®], to our portfolio. This will further augment our gastroenterology franchise and help address emerging unmet patient needs.”

Non-Alcoholic Liver Disease (NAFLD) is a spectrum ranging from non-alcoholic fatty liver (NAFLD) to Non-Alcoholic Steatohepatitis (NASH), which has the propensity to progress to liver cirrhosis and hepatocellular carcinoma (HCC) a leading cause of liver transplant. Nearly 25-30 % of the adult population in India is estimated to be suffering from NAFLD¹. Of this, almost 59.10% are estimated to be suffering from NASH². A progressive disease of the liver NAFLD starts with fat accumulation in the liver in patients who do not consume alcohol or take it in insignificant amounts, but have risk factors such as overweight or obesity, diabetes mellitus (high blood sugar), hypertension (high blood pressure) or dyslipidemia (abnormal blood lipids).

Saroglitazar Mg is uniquely poised with its dual PPAR alpha and gamma properties. In March 2020, Saroglitazar Mg received approval for the treatment of NASH. Later that year, the drug was also approved for the treatment of NAFLD. It now offers a safe and efficacious way to treat NASH and NAFLD. Zydus continues to market the drug under brand names Lipaglyn[®] and Bilypsa[®]. The novel drug 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. Since then, over 15 lac patients have benefitted from this drug. It reduces co-morbidities (dyslipidemia, hypertriglyceridemia, and diabetes mellitus). In January 2020, Saroglitazar Mg was approved for treating Type 2 Diabetes Mellitus.

^{1,2} <https://www.nash24x7.com/naflD-in-india-and-the-world/>

About Torrent

Torrent Pharma, with annual revenue of more than Rs 9,600 crores, is the flagship Company of the Torrent Group, with group revenue of ~Rs. 37,000 crores. It is ranked 6th in the Indian Pharmaceuticals Market and is amongst the Top 5 in the therapeutics segments of Cardiovascular (CV), Gastro Intestinal (GI), Central Nervous System (CNS), Vitamins Minerals Nutritional (VMN) and Cosmo-Dermatology. It is a specialty-focused company with ~75% of its revenue in India from chronic & sub- chronic therapies. It has presence in 50+ countries and is ranked No. 1 amongst the Indian pharma Companies in Brazil, Germany and Philippines. Torrent has 8 manufacturing facilities, of which 5 are USFDA approved. With R&D as the backbone for its

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growth in domestic & overseas market, it has invested significantly in R&D capabilities with state-of-the-art R&D infrastructure employing approximately 750 + scientists.

About Zydus

Zydus Lifesciences Ltd. with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global lifesciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs 25,000 people worldwide, including 1,400 scientists engaged in R & D, and is driven by its mission to unlock new possibilities in lifesciences through quality healthcare solutions that impact lives. The group aspires to transform lives through path-breaking discoveries. Over the last decade, Zydus has introduced several innovative, first-in-class products in the market for treating unmet healthcare needs with vaccines, therapeutics, biologicals and biosimilars. For more details visit www.zyduslife.com

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