

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

- *Saroglitazar Mg, is an innovative drug from Zydus approved by the DCGI to treat chronic liver diseases such as, Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steato Hepatitis (NASH). 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 NAFLD and NASH anywhere else in the world.*
- *Lupin will market the drug under the brand name LINVAS®.*
- *Zydus continues to market the drug under the brand names Lipaglyn® and Bilypsa®.*

Ahmedabad, November 03, 2023

Zydus Lifesciences Limited (including its subsidiaries/affiliates hereafter referred to as “Zydus”) a discovery-driven, global lifesciences company and Lupin Limited (Lupin), a global pharma major, today announced that they have entered into a licensing and supply agreement to co-market, Saroglitazar Mg for the treatment of Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steato Hepatitis (NASH) in India. 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, Lupin will have semi-exclusive rights to co-market the product in India under the brand name LINVAS®. Zydus launched the drug under the brand names Lipaglyn® and Bilypsa® and will continue to market them. Lupin will pay Zydus upfront licensing fees and milestone payments based on the achievement of pre-defined milestones.

In India, NAFLD is not only a concern for obese or patients with Diabetes Mellitus, but it has also been observed that NAFLD can develop in the absence of obesity, which is termed "lean" NAFLD. The number of NAFLD/NASH patients has significantly increased due to the growth in obesity and other lifestyle-related illnesses.

Speaking on the development, Managing Director, Zydus Lifesciences Ltd., Dr. Sharvil Patel said, “Our life changing discoveries are empowering patients, enabling them to live healthier and more fulfilled lives. Saroglitazar Mg which is one of the critical treatments for patients with NAFLD and NASH has substantially improved the patients’ quality of life. We are pleased to join hands with Lupin to enable access to this novel drug and thereby expand the reach.”

"We are excited to partner with Zydus to market Saroglitazar Mg for the treatment of NAFLD/NASH. This partnership reaffirms our commitment to grow and expand our offerings to meet unmet needs of patients in India. This partnership will further enhance our



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For further information please contact :  
**The Corporate Communications Department**

**Zydus Lifesciences Limited**  
(formerly known as Cadila Healthcare Limited)

Regd. Office : 'Zydus Corporate Park',  
Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar),  
Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382  
481, Gujarat, India. | Phone : +91-79-71800000,  
+91-79-48040000 | website : www.zyduslife.com  
CIN : L24230GJ1995PLC025878

gastroenterology portfolio, offering better access to healthcare options to our patients and medical professionals," said Nilesh Gupta, Managing Director, Lupin.

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 NAFLD<sup>1</sup>. Of this, almost 59.10% are estimated to be suffering from NASH<sup>2</sup>. 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. 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. 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 NAFLD and NASH. Zydus continues to market the drug under brand names Lipaglyn<sup>®</sup> and Bilypsa<sup>®</sup>.

<sup>1,2</sup> <https://www.nash24x7.com/nafld-in-india-and-the-world/>

### **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](http://www.zyduslife.com)

### **About Lupin**

Lupin is an innovation-led transnational pharmaceutical company headquartered in Mumbai, India. The Company develops and commercializes a wide range of branded and generic formulations, biotechnology products, and APIs in over 100 markets in the U.S., India, South Africa, and across the Asia Pacific (APAC), Latin America (LATAM), Europe, and Middle East regions.



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The Company enjoys a leadership position in the cardiovascular, anti-diabetic, and respiratory segments and has a significant presence in the anti-infective, gastro-intestinal (GI), central nervous system (CNS), and women's health areas. Lupin is the third-largest pharmaceutical company in the U.S. by prescriptions. The company invested 7.9% of its revenue in research and development in FY23.

Lupin has 15 manufacturing sites, 7 research centers, more than 20,000 professionals working globally, and has been consistently recognized as a 'Great Place to Work' in the Biotechnology & Pharmaceuticals sector.

**Contacts: Zydus**

**Media**

**Sujatha Rajesh**

Email: [sujatha.rajesh@zyduslife.com](mailto:sujatha.rajesh@zyduslife.com)

Mobile: 9974051180

**Investors**

**Arvind Bothra**

Email: [arvind.bothra@zyduslife.com](mailto:arvind.bothra@zyduslife.com)

Mobile: 9833853107

**Contacts: Lupin**

**Shweta Munjal**

Vice President and Head – Corporate Communications & Sustainability

Email: [shwetamunjal@lupin.com](mailto:shwetamunjal@lupin.com)



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