



August 25, 2023

**BSE Limited**

Department of Corporate Services,  
P. J. Towers, Dalal Street,  
Mumbai Samachar Marg,  
**MUMBAI - 400 001.**

✓ **National Stock Exchange of India Limited**

Exchange Plaza,  
Bandra Kurla Complex,  
Bandra (East),  
**MUMBAI - 400 051.**

**Sub: Disclosure pursuant to Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 ('Listing Regulations').**

*Dear Sir/Madam,*

We are pleased to enclose a Press Release regarding receipt of U.S. FDA approval for the Company's Abbreviated New Drug Application for Pirfenidone Tablets, 267 mg and 801 mg, to market a generic equivalent of Esbriet<sup>®</sup> Tablets, 267 mg and 801 mg of Hoffmann La Roche Inc.

This may kindly be considered as a disclosure pursuant to Regulation 30 of the Listing Regulations.

The above is for your information and dissemination.

Thanking you,

**FOR LUPIN LIMITED**

**R. V. SATAM**  
**COMPANY SECRETARY**  
**(ACS -1 1973)**

Encl- : a/a

## **Lupin Receives Approval from U.S. FDA for Pirfenidone Tablets**

**Mumbai, Baltimore, August 25, 2023:** Global pharma major Lupin Limited (Lupin) today announced that it has received approval from the United States Food and Drug Administration (U.S. FDA) for its Abbreviated New Drug Application for Pirfenidone Tablets, 267 mg and 801 mg, to market a generic equivalent of Esbriet® Tablets, 267 mg and 801 mg of Hoffmann La Roche Inc. This product will be manufactured at Lupin's Pithampur facility in India.

Pirfenidone Tablets (RLD Esbriet®) had estimated annual sales of USD 218 million in the U.S. (IQVIA MAT June 2023).

### **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.

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.

Please visit [www.lupin.com](http://www.lupin.com) for more information.

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LinkedIn: <https://www.linkedin.com/company/lupin>

Facebook: <http://www.facebook.com/LupinWorld/>

**For further information or queries please contact –**

### **Shweta Munjal**

Vice President & Global Head – Corporate Communications & Sustainability

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

### **\*Safe Harbor Statement**

Esbriet® is the registered trademark of Genentech, Inc.