



January 23, 2024

**BSE Limited**

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

✓ **National Stock Exchange of India Limited**

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

*Dear Sir/Madam,*

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

We are pleased to enclose a Press release regarding receipt of tentative approval from the U.S. FDA for the Company's Abbreviated New Drug Application for Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg, and 20 mg, to market a generic equivalent of Xarelto<sup>®</sup> Tablets, 2.5 mg, 10 mg, 15 mg, and 20 mg, of Janssen Pharmaceuticals, 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 - 11973)**

**Encl: a/a**

## Lupin Receives Tentative Approval from U.S. FDA for Rivaroxaban Tablets USP

**Mumbai, Baltimore, January 23, 2024:** Global pharma major Lupin Limited (Lupin) today announced that it has received tentative approval from the United States Food and Drug Administration (U.S. FDA) for its Abbreviated New Drug Application for Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg, and 20 mg, to market a generic equivalent of Xarelto® Tablets, 2.5 mg, 10 mg, 15 mg, and 20 mg, of Janssen Pharmaceuticals, Inc. This product will be manufactured at Lupin's Pithampur facility in India.

Rivaroxaban Tablets USP are indicated:

- to reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation
- for treatment of deep vein thrombosis (DVT)
- for treatment of pulmonary embolism (PE)
- for reduction in the risk of recurrence of DVT or PE
- for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery
- for prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients
- to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD)
- to reduce the risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD
- for treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years
- for thromboprophylaxis in pediatric patients 2 years and older with congenital heart disease after the Fontan procedure

Rivaroxaban Tablets USP (RLD Xarelto®) had estimated annual sales of USD 8,249 million in the U.S. (IQVIA MAT November 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.



BSE: 500257

NSE: LUPIN

REUTERS: LUPIN.BO

BLOOMBERG: LPCIN

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

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

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Deputy General Manager – Corporate Communications

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***\*Safe Harbor Statement***

Xarelto® is the registered trademark of Bayer Aktiengesellschaft