



February 9, 2023

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) Regulations, 2015 (Listing Regulations).

We are pleased to enclose a Press Release as regards, receipt of U.S. FDA approval for the Company's Abbreviated New Drug Application, Glycopyrrolate Injection USP, a generic equivalent of Robinul® Injection, 0.2 mg/mL of Hikma Pharmaceuticals USA 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 Approval from US FDA for Glycopyrrolate Injection, USP

First Approval from Lupin's injectable facility in Nagpur

Mumbai, Baltimore, February 09, 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 Glycopyrrolate Injection USP, a generic equivalent of Robinul® Injection, 0.2 mg/mL of Hikma Pharmaceuticals USA Inc. The product marks the first approval from Lupin's new injectable facility in Nagpur, India.

Lupin's state-of-the-art injectable facility is designed to the highest quality standards and adheres to international regulations with advanced technology and equipment for consistent production of liquid/lyophilized vials, prefilled syringes, and cartridges. Lupin is committed to expanding its portfolio and capabilities to meet the under-served demand for injectable drugs and to continue to serve patients around the world.

"We are committed to building a strong injectable business as part of our growth strategy," said **Vinita Gupta, CEO, Lupin**. "With the approval of our Nagpur facility, we can now fast-track our injectable portfolio rollout and build upon our R&D capabilities in complex products. The approval for Glycopyrrolate clears the path for more internally manufactured injectable products."

Glycopyrrolate Injection USP, 0.2 mg/mL and 0.4 mg/2 mL (0.2 mg/mL) Single-Dose Vials and 1 mg/5 mL (0.2 mg/mL) and 4 mg/20 mL (0.2 mg/mL) Multiple-Dose Vials (RLD Robinul®) had estimated annual sales of USD 39 million in the U.S. (IQVIA MAT December 2022).

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 8.7% of its revenue in research and development in FY22.

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 for more information.

Follow us on Twitter: <https://twitter.com/LupinGlobal> | LinkedIn: <https://www.linkedin.com/company/lupin>

Press Release



BSE: 500257

NSE: LUPIN

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BLOOMBERG: LPCIN

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For further information or queries please contact –

Shweta Munjal

Vice President & Global Head – Corporate Communications

Email: shwetamunjal@lupin.com

****Safe Harbor Statement***

Robinul® is a registered trademark of Wyeth LLC.