September 03, 2025

National Stock Exchange of India Limited
Exchange Plaza,
Bandra Kurla Complex,
Bandra (East),
Mumbai - 400 051

Symbol: LUPIN

BSE Limited
P. J. Towers, Dalal Street,
Mumbai Samachar Marg,
Mumbai - 400 001

Scrip Code: Equity - 500257

Subject: Disclosure pursuant to Regulation 30 of Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015

Dear Sir/Madam,

We are pleased to enclose a Press Release as regards, receipt of approval from the U.S. FDA for the Company's Abbreviated New Drug Applications for Risperidone for extended-release injectable suspension, 25 mg per vial, 37.5 mg per vial, and 50 mg per vial, Single-Dose Vials.

The same is for your information and dissemination.

Thanking you,

For LUPIN LIMITED

AMIT KUMAR GUPTA

Digitally signed by AMIT KUMAR GUPTA
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Date: 2025.09.03 12:55:26 +05'30'

AMIT KUMAR GUPTA
COMPANY SECRETARY & COMPLIANCE OFFICER
(ACS -15754)

Encl: a/a.

Press Release

BSE: 500257 NSE: LUPIN REUTERS: LUPIN.BO BLOOMBERG: LPCIN

Lupin Receives U.S. FDA Approval for Risperidone Long-Acting Injectable, with 180-Day CGT Exclusivity, the First Product from its Nanomi's Long-Acting Injectable Platform

Mumbai, Naples, September 3, 2025: 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 (ANDA) for Risperidone for extended-release injectable suspension, 25 mg per vial, 37.5 mg per vial, and 50 mg per vial, Single-Dose Vials. This is Lupin's first product using proprietary Nanomi B.V.'s (Nanomi) technology and has a 180-day CGT exclusivity. Nanomi, a Lupin subsidiary, is focused on the development of innovative long-acting injectable (LAI) medicines to improve health outcomes for patients.

Vinita Gupta, CEO of Lupin, said, "We are very pleased with the approval of the first product from our Nanomi LAI platform. This first-cycle approval is a testament to the capabilities we have established for complex injectables across our teams in R&D, Operations and related functions. It validates our platform capabilities at Nanomi and underscores our commitment to expanding access to complex injectables for patients globally. As we execute on our strategy to evolve specialty/novel products, we plan to leverage the Nanomi platform for novel long-acting injectables that meet unmet patient needs."

Nanomi's LAI platform has demonstrated efficacy and safety in drug delivery. Its proprietary particle control technology creates uniform microspheres that deliver extended-release profiles from weeks to months, superior injectability through smaller needles, and consistent drug concentrations. The technology can provide lifecycle extension opportunities for products in development or on the market that would benefit from longer-acting formulations.

"Risperidone's U.S. FDA approval provides crucial validation of Nanomi's LAI technology platform and testifies to Lupin's ability to bring complex injectables to market," said **Dr. Shahin Fesharaki, Chief Scientific Officer of Lupin.** "This is a critical milestone that validates the capabilities of our cross-functional teams and constitutes a significant step forward in our journey to develop novel long-acting injectables across various therapeutic areas."

About the product

Risperidone for extended-release injectable suspension is bioequivalent to the reference listed drug (RLD), Risperdal Consta® Long-Acting Injection, and is indicated for the treatment of schizophrenia and as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder. Risperidone for extended-release injectable suspension (RLD Risperdal Consta®) had estimated annual sales of USD 190 million in the U.S. (IQVIA MAT July 2025).

Press Release

BSE: 500257	NSE: LUPIN	REUTERS: LUPIN.BO	BLOOMBERG: LPCIN

About Lupin

Lupin Limited is a global pharmaceutical leader headquartered in Mumbai, India, with products distributed in over 100 markets. Lupin specializes in pharmaceutical products, including branded and generic formulations, complex generics, biotechnology products, and active pharmaceutical ingredients. Trusted by healthcare professionals and consumers globally, the company enjoys a strong position in India and the U.S. across multiple therapy areas, including respiratory, cardiovascular, anti-diabetic, anti-infective, gastrointestinal, central nervous system, and women's health. Lupin has 15 state-of-the-art manufacturing sites and 7 research centers globally, along with a dedicated workforce of over 24,000 professionals. Lupin is committed to improving patient health outcomes through its subsidiaries - Lupin Diagnostics, Lupin Digital Health, and Lupin Manufacturing Solutions.

To know more, visit www.lupin.com or follow us on LinkedIn https://www.linkedin.com/company/lupin

To know more about Nanomi, visit www.nanomi.com or follow on LinkedIn https://www.linkedin.com/company/nanomi

For further information or queries, please contact

Rajalakshmi Azariah

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Safe Harbor Statement

Risperdal Consta® is a registered trademark of Johnson & Johnson.