



December 01, 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 the Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015

Dear Sir/Madam,

We are pleased to enclose a Press Release titled "Lupin Receives Approval from U.S. FDA for Biosimilar Armlupeg™ (Pegfilgrastim-unne)."

The same is for your information and dissemination.

Thanking you,

For LUPIN LIMITED

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

Encl.: a/a.

LUPIN LIMITED

Registered Office: 3rd Floor, Kalpataru Inspire, Off W. E. Highway, Santacruz (East), Mumbai - 400 055 India. **Tel:** (91-22) 6640 2323.

Corporate Identity Number: L24100MH1983PLC029442

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Lupin Receives Approval from U.S. FDA for Biosimilar Armlupeg™ (Pegfilgrastim-unne)

Mumbai, Naples, December 1, 2025: Global pharma major Lupin Limited (Lupin), today announced that the United States Food and Drug Administration (U.S. FDA) has approved Armlupeg™ (pegfilgrastim-unne) 6 mg/0.6 mL injection for subcutaneous use in a single-dose prefilled syringe, as biosimilar to Neulasta® (pegfilgrastim) 6 mg/0.6 mL injection. The product will be manufactured at Lupin's Biotech facility in Pune, which was inspected by the U.S. FDA prior to approval.

Armlupeg™ is indicated for:

- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
- Increase survival in patients acutely exposed to myelosuppressive doses of radiation.

"We are proud to achieve the FDA approval for our first biosimilar, Pegfilgrastim. This step marks a pivotal step in Lupin's ongoing commitment to providing more affordable, accessible medicines to U.S. patients. We look forward to introducing a robust portfolio of biosimilars over the next few years, which will help improve the quality of care for the communities and patients we serve," said **Vinita Gupta, CEO, Lupin.**

Nilesh Gupta, MD, Lupin, said, "Our integrated biologic capabilities encompass the entire spectrum, from initial cell line development to upstream/downstream process optimization and clinical development. This, coupled with our state-of-the-art biologic facility that has now been approved by every major regulatory body, ensures that we deliver biosimilars that meet the highest global quality standards while achieving the scale necessary for global affordability."

"We are pleased to have obtained approval for Pegfilgrastim. This milestone demonstrates Lupin's unwavering commitment to reducing barriers to treatment and empowering patients with greater choice and confidence in their healthcare journey," said **Dr. Cyrus Karkaria, President, Biotechnology, Lupin.**

Pegfilgrastim 6 mg/0.6 mL injection for subcutaneous use in a single-dose prefilled syringe had estimated annual sales of USD 1,295 million in the U.S. for the 12 months ending September 2025 (IQVIA MAT).

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

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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 22,000 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>

For further information or queries, please contact**Rajalakshmi Azariah**

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***Safe Harbor Statement**

Neulasta® is a registered trademark of Amgen Inc.