



June 2, 2021

✓ **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 the SEBI (Listing Obligations
and Disclosure Requirements) Regulations, 2015.**

Dear Sir/Madam,

Enclosed is a Press Release as regards acceptance by U.S. FDA of the Biologics License Application for the Company's proposed biosimilar to Neulasta® (pegfilgrastim) through a filing using the 351(k) pathway.

This may kindly be considered as a disclosure pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

Thanking you,

FOR LUPIN LIMITED

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

Encl- : a/a.

BSE: 500257

NSE: LUPIN

REUTERS: LUPIN.BO

BLOOMBERG: LPCIN

Lupin announces U.S. FDA acceptance for Pegfilgrastim Biosimilar application

Mumbai, Baltimore, June 2, 2021: Global pharma major, Lupin Limited (Lupin) today announced that the U.S. FDA has accepted the Biologics License Application (BLA) for its proposed biosimilar to Neulasta® (pegfilgrastim) through a filing using the 351(k) pathway.

Pegfilgrastim has estimated annual sales of USD 3.66 billion in the U.S. (IQVIA MAT December 2020).

Commenting on the development, **Vinita Gupta, CEO, Lupin** said, “FDA’s acceptance of our BLA is a significant achievement and demonstrates our commitment to delivering products which increase access in areas of substantial medical need. This BLA expands our oncology portfolio, an area of increasing focus for Lupin. We look forward to the opportunity to bring affordable biologic options to patients and increasing access to this important treatment.”

Nilesh Gupta, MD, Lupin said, “The pegfilgrastim filing is our first biosimilar filing in the U.S. and is a milestone in our research and innovation journey as we continue to focus on delivering unique and affordable solutions to alleviate disease burden. Biosimilars is a key part of our growth strategy and we are proud of the world-class achievements of our group.”

The BLA submission is supported by similarity data from analytical, pharmacokinetic, pharmacodynamic and immunogenicity studies.

Dr. Cyrus Karkaria, President, Lupin Biotech said “With significant investment in our biotechnology division over the years, we remain committed to bringing much-needed innovative products to market. This milestone further encourages us to continue advancing our robust Biosimilars pipeline across the globe to provide effective, affordable alternative for consumers.”

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 Asia Pacific (APAC), Latin America (LATAM), Europe and Middle-East regions.

The Company enjoys leadership position in the cardiovascular, anti-diabetic, and respiratory segments and has 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 9.6% of its revenue on research and development in FY21.

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Lupin has 15 manufacturing sites, 7 research centres, 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>

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

For further information or queries please contact –

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