



December 15, 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) 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, Sitagliptin Tablets USP, 25 mg, 50 mg, and 100 mg to market a generic equivalent of Januvia Tablets, 25 mg, 50 mg, and 100 mg, of Merck Sharp and Dohme Corp.

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 Sitagliptin Tablets

Mumbai, Baltimore, December 15, 2023: 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 (ANDA), Sitagliptin Tablets USP, 25 mg, 50 mg, and 100 mg to market a generic equivalent of Januvia Tablets, 25 mg, 50 mg, and 100 mg, of Merck Sharp and Dohme Corp. (Merck). This product will be manufactured at Lupin's Pithampur facility in India.

Sitagliptin Tablets USP, 25 mg, 50 mg, and 100 mg are indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus.

Sitagliptin Tablets (RLD Januvia®) had estimated annual sales of USD 5789.3 million in the U.S. (IQVIA MAT October 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.

Please visit www.lupin.com for more information.

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LinkedIn: <https://www.linkedin.com/company/lupin>

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

Twitter: <https://twitter.com/LupinGlobal>

For further information or queries please contact –

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****Safe Harbor Statement***

Januvia® is a registered trademark of Merck Sharp and Dohme Corp.LLC