



November 7, 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 for Canagliflozin and Metformin Hydrochloride Extended-Release Tablets, 50 mg/500 mg, 50 mg/1,000 mg, 150 mg/500 mg, and 150 mg/1,000 mg to market a generic equivalent of Invokamet XR[®] Tablets, 50 mg/500 mg, 50 mg/1,000 mg, 150 mg/500 mg, and 150 mg/1,000 mg, of Janssen Pharmaceuticals, 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 Tentative Approval from U.S. FDA for Canagliflozin and Metformin Hydrochloride Extended-Release Tablets

Mumbai, Baltimore, November 07, 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 for Canagliflozin and Metformin Hydrochloride Extended-Release Tablets, 50 mg/500 mg, 50 mg/1,000 mg, 150 mg/500 mg, and 150 mg/1,000 mg to market a generic equivalent of Invokamet XR[®] Tablets, 50 mg/500 mg, 50 mg/1,000 mg, 150 mg/500 mg, and 150 mg/1,000 mg, of Janssen Pharmaceuticals, Inc. This product will be manufactured at Lupin's Pithampur facility in India.

- Canagliflozin and Metformin Hydrochloride Extended-Release Tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- Canagliflozin is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.
- Canagliflozin is indicated to reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day.

Canagliflozin and Metformin Hydrochloride Extended-Release Tablets (RLD Invokamet XR[®]) had estimated annual sales of USD 28 million in the U.S. (IQVIA MAT July 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.



BSE: 500257

NSE: LUPIN

REUTERS: LUPIN.BO

BLOOMBERG: LPCIN

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**For further information or queries please contact –
Shweta Munjal**

Vice President & Global Head – Corporate Communications & Sustainability

Email: shwetamunjal@lupin.com

****Safe Harbor Statement***

Invokamet XR® is the registered trademark of Johnson & Johnson.