



November 23, 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 U.S. FDA, for the Company's Abbreviated New Drug Application for Canagliflozin Tablets, 100 mg and 300 mg, to market a generic equivalent of Invokana[®] Tablets, 100 mg and 300 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 Tablets

Mumbai, Baltimore, November 23, 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 Tablets, 100 mg and 300 mg, to market a generic equivalent of Invokana® Tablets, 100 mg and 300 mg, of Janssen Pharmaceuticals, Inc. This product will be manufactured at Lupin's Pithampur facility in India.

Canagliflozin is a sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated:

- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
- to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease
- 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

Canagliflozin Tablets (RLD Invokana®) had estimated annual sales of USD 561 million in the U.S. (IQVIA MAT September 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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For further information or queries please contact –

Shweta Munjal

Vice President & Global Head – Corporate Communications & Sustainability

Email: shwetamunjal@lupin.com

****Safe Harbor Statement***

Invokana® is the registered trademark of Johnson & Johnson