



January 14, 2024

**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) Regulations, 2015 ('Listing Regulations').**

We are pleased to enclose a Press Release as regards, receipt of U.S. FDA approval for the Company's Abbreviated New Drug Application for Propranolol Hydrochloride Extended-Release Capsules USP, 60 mg, 80 mg, 120 mg, and 160 mg, to market a generic equivalent of Inderal® LA Extended-Release Capsules, 60 mg, 80 mg, 120 mg, and 160 mg, of ANI 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 Approval from U.S. FDA for Propranolol Hydrochloride Extended-Release Capsules USP

**Mumbai, Baltimore, January 14, 2024:** Global pharma major Lupin Limited (Lupin) today announced that it has received approval from the United States Food and Drug Administration (U.S. FDA) for its Abbreviated New Drug Application for Propranolol Hydrochloride Extended-Release Capsules USP, 60 mg, 80 mg, 120 mg, and 160 mg, to market a generic equivalent of Inderal® LA Extended-Release Capsules, 60 mg, 80 mg, 120 mg, and 160 mg, of ANI Pharmaceuticals, Inc. The product will be manufactured at Lupin's Pithampur facility in India.

Propranolol Hydrochloride Extended-Release Capsules USP, 60 mg, 80 mg, 120 mg, and 160 mg are indicated for:

- **Hypertension**

Propranolol Hydrochloride Extended-Release Capsules USP are indicated in the management of hypertension. They may be used alone or used in combination with other antihypertensive agents, particularly a thiazide diuretic. Propranolol Hydrochloride Extended-Release Capsules USP are not indicated in the management of hypertensive emergencies.

- **Angina Pectoris Due to Coronary Atherosclerosis**

Propranolol Hydrochloride Extended-Release Capsules USP are indicated to decrease angina frequency and increase exercise tolerance in patients with angina pectoris.

- **Migraine**

Propranolol Hydrochloride Extended-Release Capsules USP are indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established, and propranolol is not indicated for such use.

- **Hypertrophic Subaortic Stenosis**

Propranolol Hydrochloride Extended-Release Capsules USP improve NYHA functional class in symptomatic patients with hypertrophic subaortic stenosis.

Propranolol Hydrochloride Extended-Release Capsules USP (RLD Inderal® LA) had estimated annual sales of USD 71 million in the U.S. (IQVIA MAT November 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



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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](http://www.lupin.com) for more information.

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

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

**For further information or queries please contact –  
Heena Dhedhi**

Deputy General Manager - Corporate Communications

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***\*Safe Harbor Statement***

INDERAL® LA is a registered trademark of ANI Pharmaceuticals, Inc.