



March 17, 2025

**National Stock Exchange of India Limited**

Exchange Plaza,  
Bandra Kurla Complex,  
Bandra (East),  
Mumbai - 400 051

**Symbol: LUPIN**

**BSE Limited**

P. J. Towers, Dalal Street,  
Mumbai Samachar Marg,  
Mumbai - 400 001

**Scrip Code: Equity - 500257**

**Subject: Disclosure pursuant to Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 ('Listing Regulations').**

***Dear Sir/Madam,***

We are pleased to enclose a Press Release as regards, receipt of tentative approval from the U.S. FDA for the Company's Abbreviated New Drug Application for Amifampridine Tablets, 10 mg.

The same is for your information and dissemination.

Thanking you,

**For LUPIN LIMITED**

**AMIT KUMAR GUPTA  
COMPANY SECRETARY & COMPLIANCE OFFICER  
(ACS -15754)**

**Encl: a/a.**

LUPIN LIMITED

Registered Office: 3<sup>rd</sup> Floor, Kalpataru Inspire, Off W. E. Highway, Santacruz (East), Mumbai - 400 055 India. Tel: (91-22) 6640 2323.

Corporate Identity Number: L24100MH1983PLC029442

[www.lupin.com](http://www.lupin.com)

## **Lupin Receives Tentative Approval from U.S. FDA for Amifampridine Tablets**

**Mumbai, Naples, March 17, 2025:** 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 Amifampridine Tablets, 10 mg. This product would be manufactured at Lupin's Goa facility in India.

Amifampridine Tablets, 10 mg, are bioequivalent to Firdapse® Tablets, 10 mg of Catalyst Pharmaceuticals, Inc., and are indicated for the treatment of Lambert-Eaton myasthenic syndrome in adults and pediatric patients 6 years of age and older.

Amifampridine Tablets, 10 mg (RLD Firdapse®) had an estimated global net sale of USD 306 million for the fiscal year ended December 31, 2024.

### **About Lupin**

Lupin Limited is a global pharmaceutical leader headquartered in Mumbai, India, with products distributed in over 100 markets. Lupin specializes in pharmaceutical products, including branded and generic formulations, complex generics, biotechnology products, and active pharmaceutical ingredients. Trusted by healthcare professionals and consumers globally, the company enjoys a strong position in India and the U.S. across multiple therapy areas, including respiratory, cardiovascular, anti-diabetic, anti-infective, gastrointestinal, central nervous system, and women's health. Lupin has 15 state-of-the-art manufacturing sites and 7 research centers globally, along with a dedicated workforce of over 23,000 professionals. Lupin is committed to improving patient health outcomes through its subsidiaries - Lupin Diagnostics, Lupin Digital Health, and Lupin Manufacturing Solutions.

To know more, visit [www.lupin.com](http://www.lupin.com) or follow us on LinkedIn <https://www.linkedin.com/company/lupin>

For further information or queries please contact:

**Rajalakshmi Azariah**

**Vice President & Global Head – Corporate Communications, Lupin**

[rajalakshmiazariah@lupin.com](mailto:rajalakshmiazariah@lupin.com)

### **\*Safe Harbor Statement**

Firdapse® is a registered trademark of SERB