



October 12, 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 the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 ('Listing Regulations').

We are pleased to enclose a Press Release as regards, receipt of tentative U.S. FDA approval for the Company's Abbreviated New Drug Application, Calcium, Magnesium, Potassium and Sodium Oxybates Oral Solution, 0.5 g/mL, to market a generic equivalent of Xywav® Oral Solution, 0.5 g/mL of Jazz Pharmaceuticals Ireland Limited.

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 Calcium, Magnesium, Potassium, and Sodium Oxybates Oral Solution

Mumbai, Baltimore, October 12, 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 Calcium, Magnesium, Potassium, and Sodium Oxybates Oral Solution, 0.5 g/mL, to market a generic equivalent of Xywav[®] Oral Solution, 0.5 g/mL of Jazz Pharmaceuticals Ireland Limited. This product will be manufactured at Lupin's Somerset facility in the US.

Lupin is exclusive first-to-file and may be eligible to receive a 180-day exclusivity period at product launch.

The net product sales for Calcium, Magnesium, Potassium, and Sodium Oxybates Oral Solution (RLD Xywav[®]) were USD 958.4 million for the year ending December 2022 and USD 604.3 million for the first six months of 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.

Follow us on:

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 –
Shweta Munjal**

Vice President & Global Head – Corporate Communications & Sustainability

Email: shwetamunjal@lupin.com

***Safe Harbor Statement**

Xywav[®] is the registered trademark of Jazz Pharmaceuticals Ireland Limited