



December 27, 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 U.S. FDA approval for the Company's Abbreviated New Drug Application for Loteprednol Etabonate Ophthalmic Suspension, 0.2%, to market a generic equivalent to the reference listed drug Alex<sup>®</sup> Ophthalmic Suspension, 0.2%, of Bausch & Lomb 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 Loteprednol Etabonate Ophthalmic Suspension, 0.2%**

**Mumbai, Baltimore, December 27, 2023:** 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 Loteprednol Etabonate Ophthalmic Suspension, 0.2%, to market a generic equivalent to the reference listed drug (RLD) Alex<sup>®</sup> Ophthalmic Suspension, 0.2%, of Bausch & Lomb Inc. The product will be manufactured at Lupin's Pithampur facility in India.

Loteprednol Etabonate Ophthalmic Suspension, 0.2%, is indicated for the temporary relief of the signs and symptoms of seasonal allergic conjunctivitis.

Loteprednol Etabonate Ophthalmic Suspension, 0.2% (RLD Alex<sup>®</sup>), had estimated annual sales of USD 29.1 million in the U.S. (IQVIA MAT October 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](http://www.lupin.com) for more information.

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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

Email: [shwetamunjal@lupin.com](mailto:shwetamunjal@lupin.com)

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

Alex<sup>®</sup> is a registered trademark of Bausch & Lomb Incorporated or its affiliates.