



October 6, 2021

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.

Sub: Disclosure pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

Dear Sir/Madam,

Enclosed is a Press Release as regards receipt of tentative U.S. FDA approval for the Company's Abbreviated New Drug Application (ANDA) Brexpiprazole Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg, to market a generic equivalent of Rexulti® Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg, of Otsuka Pharmaceutical Co., Ltd.

This may kindly be considered as a disclosure pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

Thanking you,

Yours faithfully,
For LUPIN LIMITED

R. V. SATAM
COMPANY SECRETARY
(ACS - 11973)



Encl.: a/a

LUPIN LIMITED

Registered Office: 3rd 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



Lupin Receives Tentative Approval from U.S. FDA for Brexpiprazole Tablets

Mumbai, Baltimore, October 6, 2021: Global pharma major Lupin Limited (Lupin) today announced that it has received tentative approval from the United States Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) Brexpiprazole Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg, to market a generic equivalent of Rexulti® Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg, of Otsuka Pharmaceutical Co., Ltd. This product will be manufactured at Lupin's Pithampur facility in India.

Brexpiprazole Tablets (RLD: Rexulti® Tablets) had estimated annual sales of USD 1258 million in the U.S. (IQVIA MAT July 2021).

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 Asia Pacific (APAC), Latin America (LATAM), Europe and Middle-East regions.

The Company enjoys leadership position in the cardiovascular, anti-diabetic, and respiratory segments and has 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 9.6% of its revenue on research and development in FY21.

Lupin has 15 manufacturing sites, 7 research centres, 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 Twitter: <https://twitter.com/LupinGlobal> | LinkedIn: <https://www.linkedin.com/company/lupin>

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

For further information or queries please contact –

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Head – Corporate Communications

Email: shwetamunjal@lupin.com

***Safe Harbor Statement**

Rexulti® is a registered trademark of Otsuka Pharmaceutical Co. Ltd.