



February 12, 2019

✓ **BSE Limited,**

Department of Corporate Services,  
P. J. Towers, Dalal Street,  
Mumbai Samachar Marg,  
**MUMBAI - 400 001.**

**The National Stock Exchange of India Ltd.,**

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.**

Enclosed is a Press Release as regards receipt of USFDA approval for Fluoxetine Tablets USP, 60mg, to market a generic version of Alvogen's Fluoxetine Tablets, 60mg.

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**



Encl.: a.a.

### Lupin receives FDA approval for Fluoxetine Tablets USP

**Mumbai, Baltimore, February 12, 2019:** Pharma major Lupin announced that it has received approval for its Fluoxetine Tablets USP, 60mg, from the United States Food and Drug Administration (FDA) to market a generic version of Alvogen's Fluoxetine Tablets, 60mg.

Lupin's Fluoxetine Tablets USP, 60mg, is the generic version of Alvogen's Fluoxetine Tablets, 60mg. It is indicated in the treatment of:

- Major Depressive Disorder (MDD).  
Adults: Efficacy was established in one 5-week trial, three 6-week trials, and one maintenance study.  
Pediatrics: Efficacy was established in two 8- to 9-week trials of patients 8 to 18 years of age.
- Obsessive Compulsive Disorder (OCD).  
Adults: Efficacy was established in two 13-week trials.  
Pediatrics: Efficacy was established in one 13-week trial in pediatric patients 7 to 17 years of age.
- Bulimia Nervosa  
Adults: Efficacy was established in two 8-week trials and one 16-week trial.
- Panic disorder, with or without agoraphobia  
Adults: Efficacy was established in two 12-week trials.

Fluoxetine Tablets, 60mg, had annual sales of approximately USD 42.5 million in the US (IQVIA MAT December 2018).

#### About Lupin Limited

Lupin is an innovation led transnational pharmaceutical company developing and delivering a wide range of branded & generic formulations, biotechnology products and APIs globally. The Company is a significant player in the Cardiovascular, Diabetology, Asthma, Pediatric, CNS, GI, Anti-Infective and NSAID space and holds global leadership position in the Anti-TB segment.

Lupin is the 8<sup>th</sup> largest generics pharmaceutical company in terms of market capitalization (28<sup>th</sup> December 2018, Bloomberg) and the 8<sup>th</sup> largest generics pharmaceutical company in terms of revenues (30<sup>th</sup> September 2018, Bloomberg LTM) globally. The Company is the 3<sup>rd</sup> largest pharmaceutical player in the US by prescriptions for the Total Market (IQVIA MAT December 2018); 3<sup>rd</sup> largest Indian pharmaceutical company by global revenues (30<sup>th</sup> September 2018, Bloomberg LTM); 6<sup>th</sup> largest generic pharmaceutical player in Japan (IQVIA MAT December 2018) and 5<sup>th</sup> largest company in the Indian Pharmaceutical Market (IQVIA MAT December 2018).

For the financial year ended 31<sup>st</sup> March, 2018, Lupin's Consolidated sales and Net profits before exceptional items were at Rs.155,598 million (USD 2.41 billion) and Rs.13,934 million (USD 216 million) respectively. Please visit <http://www.lupin.com> for more information. You could also follow us on Twitter – [www.twitter.com/lupinglobal](http://www.twitter.com/lupinglobal)

CIN: L24100MH1983PLC029442 Registered Office: Lupin Ltd, 3rd Floor, Kalpataru Inspire, Off Western Express Highway, Santacruz (East), Mumbai 400 055.

## Press Release



For further information or queries please contact –

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*\*Safe Harbor Statement*