Press Release

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

For the financial year ended 31st 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

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

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For further information or queries please contact –

Pooja Thakran
VP – Corporate Communications
Email: poojathakran@lupin.com
Ph: +91-22-66402531 / 8291013225

Arvind Bothra
Head – Investor Relations
Email: arvindbothra@lupin.com
Ph: +91-22-66408237

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