Press Note

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U.S. FDA completes inspection of Lupin's Nagpur facility

Mumbai, January 11, 2020: Pharma major Lupin Limited (Lupin) today announced the completion of a PAI (Prior Approval Inspection) carried out by the United States Food and Drug Administration (U.S. FDA) at its Nagpur oral solid dosage manufacturing facility. The inspection was carried out between January 6, 2020 and January 10, 2020.

The inspection closed with two 483 observations.

Commenting on the outcome of the inspection, **Nilesh Gupta, Managing Director, Lupin** said, *"We are committed to meeting the highest quality standards and are committed to full compliance with CGMP regulations at all our manufacturing facilities. The Nagpur facility is our latest oral solid dosage facility, and this was the seventh U.S. FDA inspection at the facility. We will address the observations raised by the agency satisfactorily and will submit our comprehensive response within the stipulated timeline"*.

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 by revenues (June 30, 2019, Bloomberg LTM). The Company is the 3rd largest pharmaceutical player in the US by prescriptions (IQVIA MAT September 2019); 3rd largest Indian pharmaceutical company by global revenues (June 30, 2019, Bloomberg LTM); and 6th largest company in the Indian Pharmaceutical Market (IQVIA MAT September 2019).

For the financial year ended March 31, 2019, Lupin's Consolidated sales and Net profits before exceptional items were at INR 163,694 million (USD 2.34 billion) and INR 9,466 million (USD 136 million) respectively. Please visit http://www.lupin.com for more information. You could also follow us on LinkedIn and Facebook at https://www.linkedin.com/company/lupinglobal/ and https://www.facebook.com/Lupin-Global respectively.

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

For further information or queries please contact:

Arvind Bothra
Head – Investor Relations and M&A / Corporate Communications
Email: arvindbothra@lupin.com |
Ph: +91-22-66408237