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US FDA completes inspection of Lupin's Mandideep location

Mumbai, December 5, 2018: Pharma major Lupin announced today the completion of United States Food and Drug Administration (US FDA) inspections carried out at its Mandideep location. Lupin's Mandideep location houses the company's cardiovascular "Pril" API facilities, Cephalosporin API facilities and Cephalosporin Solid Oral Dosage Form facility. These inspections were carried out between November 26 and December 4, 2018.

The inspection at Unit-2, the Cardiovascular "Pril" API facilities closed with 4 observations.

The inspection at Unit-1, the Cephalosporin facilities closed with 10 observations for the Cephalosporin API facilities and 8 observations for the Cephalosporin Solid Oral Dosage Form facility.

The observations are largely procedural in nature with some gaps identified in the aseptic processing areas of the Cephalosporin API block and the company is confident of addressing them satisfactorily.

As a company, Lupin has committed to an enhanced Quality Management System and Compliance Sustainability Plan. The Lupin Mandideep site is already executing the plan, which also serves to address some of the concerns raised during this inspection.

There are no new DMF and ANDA applications pending for review or approval from Lupin's Mandideep facilities.

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 13th largest generics pharmaceutical company in terms of market capitalization (30th September 2018, Bloomberg) and the 8th largest generics pharmaceutical company in terms of revenues (30th June 2018, Bloomberg LTM) globally. The Company is the 3rd largest pharmaceutical player in the US by prescriptions for the Total Market (IQVIA MAT September 2018); 3rd largest Indian pharmaceutical company by global revenues (30th June 2018, Bloomberg LTM); 6th largest generic pharmaceutical player in Japan (IQVIA MAT September 2018) and 5th largest company in the Indian Pharmaceutical Market (IQVIA MAT September 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

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