Press Release

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Lupin's Tarapur API Manufacturing Facility Inspected by US FDA

Mumbai, September 4, 2018: Pharma major Lupin announced today the completion of a cGMP inspection carried out by the US FDA at its Tarapur facility. The inspection closed with one observation, a procedural deficiency. The inspection at the site was conducted between 27th and 31st August 2018 by three FDA investigators.

The inspection focused on cGMP compliance and also on the safety of Lupin's Valsartan, Losartan and Irbesartan APIs (commonly known as 'Sartans') in light of the safety alert issued by Regulatory Authorities on the NDMA (classified as a probable human carcinogen) impurity in Valsartan API supplied by some companies. During the inspection, the US FDA concluded that the manufacturing processes of Lupin 'Sartans' are safe with no chance of presence of the NDMA impurity in the APIs.

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 both in terms of market capitalization (30th June 2018, Bloomberg) and revenues (31st March 2018, Bloomberg LTM) globally. The Company is the 4th largest pharmaceutical player in the US by prescriptions (IQVIA MAT June 2018); 3rd largest Indian pharmaceutical company by global revenues (31st March 2018, Bloomberg LTM); 6th largest generic pharmaceutical player in Japan and 5th largest company in the Indian Pharmaceutical Market (IQVIA MAT June 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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