

Lupin Receives Tentative Approval for Generic Zorvolex® Capsules

Mumbai, Baltimore, December 06, 2016: Pharma Major Lupin Limited announced today that its US subsidiary, Lupin Pharmaceuticals, Inc. (collectively Lupin) has received tentative approval for its Diclofenac Capsules USP, 18 mg and 35 mg from the United States Food and Drug Administration (FDA) to market a generic version of Iroko Pharmaceuticals LLC's Zorvolex® Capsules 18 mg and 35 mg.

Lupin's Diclofenac Capsules USP, 18 mg and 35 mg are the AB rated generic equivalent of Iroko Pharmaceuticals LLC's Zorvolex® Capsules 18 mg and 35 mg. It is indicated for management of mild to moderate acute pain and management of osteoarthritis pain.

Zorvolex® Capsules had US sales of USD 39.6 million (IMS MAT September 2016).

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 6th and the 8th largest generics pharmaceutical company by market capitalization and sales globally (September 30th, 2016, Bloomberg). The Company is the 5th largest pharmaceutical player in the US by prescriptions (4.68% market share – IMS Health, National Prescription Audit, March 2016); the 3rd largest Indian pharmaceutical company by revenues; the 6th largest generic pharmaceutical player in Japan and the 4th largest generic pharmaceutical company in South Africa (IMS Health, March 2016).

For the financial year ended 31st March, 2016, Lupin's Consolidated sales and Net profit stood at Rs. 136,539 million (USD 2.09 billion) and Rs. 22,607 million (USD 345 million) respectively. Please visit <http://www.lupin.com> for more information. You could also follow us on Twitter - www.twitter.com/lupinlimited

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Press Release



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[*Safe Harbor Statement](#)

Zorvolex® is the registered trademark of Iroko Pharmaceuticals LLC.