



BSE: 500257

NSE: LUPIN

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Lupin Receives FDA Approval for Hydrocodone Bitartrate and Acetaminophen Tablets

Mumbai, November 17, 2016: Pharma Major Lupin Limited announced today that its US subsidiary, Gavis Pharmaceuticals LLC., U.S.A. (collectively Lupin) has received final approval for its Hydrocodone Bitartrate and Acetaminophen Tablets USP, 5mg/300 mg, 7.5 mg/300 mg & 10 mg/300 mg from the United States Food and Drug Administration (FDA) to market a generic equivalent of Mikart, Inc's Hydrocodone Bitartrate and Acetaminophen Tablets USP, 5 mg/300 mg, 7.5 mg/300 mg & 10 mg/300 mg.

Lupin's Hydrocodone Bitartrate and Acetaminophen Tablets USP, 5 mg/300 mg, 7.5 mg/300 mg & 10 mg/300 mg are the AA rated generic equivalent of Mikart, Inc's Hydrocodone Bitartrate and Acetaminophen Tablets USP, 5 mg/300 mg, 7.5 mg/300 mg & 10 mg/300 mg. It is indicated for the relief of moderate to moderately severe pain.

Hydrocodone Bitartrate and Acetaminophen Tablets USP had US sales of USD 89.6 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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