

Press Release



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Lupin Receives FDA Approval for Generic Ranexa® Extended-release Tablets

Mumbai, Baltimore, August 01, 2013: Pharma Major Lupin Limited announced today that its U.S. subsidiary, Lupin Pharmaceuticals, Inc. (LPI) has received final approval for its Ranolazine Extended-release tablets, 500 mg and 1000 mg from the United States Food and Drugs Administration (FDA).

Lupin's Ranolazine Extended-release tablets are the AB-rated generic equivalent of Gilead Sciences, Inc.'s (Gilead) Ranexa® Extended-release tablets, 500 mg and 1000 mg strengths. Ranolazine Extended-release tablets is indicated for treatment of chronic angina.

Ranexa® tablets, 500 mg and 1000 mg had U.S sales of approximately **USD 443.4 million**, for the twelve months ending March, 2013 (IMS Health data).

Lupin believes that it is the first applicant to file an ANDA for Ranexa® Extended-release tablets 500 mg and 1000 mg strengths and as such will be entitled to 180 days of marketing exclusivity.

About Lupin Limited

Headquartered in Mumbai, Lupin is an innovation led transnational pharmaceutical company producing and developing a wide range of branded and generic formulations 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 positions in the Anti-TB and Cephalosporin segment.

Lupin is the 5th largest and fastest growing top 5 generics player in the US (5.3% market share by prescriptions, IMS Health) and the 3rd largest Indian pharmaceutical company by sales. The Company is also the fastest growing top 10 generic pharmaceutical players in Japan and South Africa (IMS).

For the financial year ended March 2013, Lupin's Consolidated turnover and Profit after Tax were Rs. 94,616 million (USD 1.74 billion) and Rs. 13,142 million (USD 242 million) respectively. Please visit <http://www.lupinworld.com> for more information.

Lupin Pharmaceuticals, Inc. is the wholly owned U.S. subsidiary of Lupin Limited. Headquartered in Baltimore, Maryland, Lupin Pharmaceuticals, Inc. is dedicated to delivering high-quality, affordable generic medicines and branded formulations trusted by healthcare professionals and patients across geographies. For more information, visit <http://www.lupinpharmaceuticals.com>

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Safe Harbor Statement

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