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NSE: LUPIN

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Lupin receives FDA approval for Generic Glumetza® extended-release Tablets

Mumbai, Baltimore, July 22, 2013: Pharma Major Lupin Limited announced today that its U.S. subsidiary, Lupin Pharmaceuticals, Inc. (LPI) has received final approval for its Metformin Hydrochloride extended release tablets (HCl ER) 500 mg and 1000 mg from the United States Food and Drugs Administration (FDA).

Lupin's Metformin HCl ER Tablets, 500 mg and 1000 mg strengths are the AB-rated generic equivalent of Santarus, Inc.'s Glumetza® HCl ER Tablets, 500 mg and 1000 mg strengths. Metformin HCl ER tablets is a biguanide and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Glumetza® HCl ER tablets, 500 mg and 1000 mg had U.S sales of approximately US\$ 144 million, for the twelve months ending March, 2013 (IMS Health data). Lupin had earlier received the tentative approval for generic GLUMETZA® (Metformin Hydrochloride Extended Release Tablets) 1000 mg and 500 mg from the United States Food and Drugs Administration (FDA) in January, 2012.

Lupin believes that it is the first applicant to file an ANDA for Glumetza® HCL ER Tablets, 500 mg & 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>

For further information or queries please contact -

Shamsher Gorawara

Head – Corporate Communications

Lupin Limited

Ph: +91 98 20 338 555

Email: shamshergorawara@lupinpharma.com

or

Press Release



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Rajiv Pillai
Head – Investor Relations
Lupin Limited
Ph: +91 98 20 552 083
Email: rajivpillai@lupinpharma.com

Safe Harbor Statement

**Glumetza Extended-release Tablets, 500 mg & 1000 mg are registered copyright of Santarus, Inc.*