Press Release



BSE: 500257 NSE: LUPIN REUTERS: LUPIN.BO BLOOMBERG: LPC IN

Lupin Receives FDA Approval for Generic Monodox® Capsules and Cipro® for Oral Suspension

Mumbai, Baltimore, March 06, 2014: Pharma Major Lupin Limited (Lupin) announced today that it has received final approval for its Doxycycline Capsules USP, 50 mg, 75 mg, and 100 mg from the United States Food and Drugs Administration (FDA) to market a generic version of Aqua Pharmaceuticals Monodox® Capsules 50 mg, 75 mg, and 100 mg.

Lupin's Doxycycline Capsules 50mg, 75mg and 100mg are the AB-rated generic equivalents of Aqua Pharmaceuticals, LLC's Monodox® Capsules 50mg, 75mg and 100mg and are indicated in the treatment of infections caused by various microorganisms and as an adjunctive therapy in severe acne.

The Company also received final approval from the FDA for its Ciprofloxacin for Oral Suspension, 5 g/100 mL (250 mg/5 mL) and 10 g/100 mL (500 mg/5 mL) to market a generic version of Bayer HealthCare Pharmaceuticals, Inc.'s (Bayer) Cipro $^{\circ}$ for Oral Suspension 5 g/100 mL and 10 g/100 mL.

Lupin's Ciprofloxacin Oral Suspension, 5 g/100 mL (250 mg/5 mL) and 10 g/100 mL (500 mg/5 mL) is the generic equivalent of Bayer's Cipro® Oral Suspension 5 g/100 mL (250 mg/5 mL) and 10 g/100 mL (500 mg/5 mL) and indicated for the treatment of infections caused by susceptible isolates of the designated microorganisms in various conditions and patient populations.

Lupin is the first applicant to file an ANDA for Cipro® Oral Suspension 250 mg/ml & 500 mg/ml and as such is entitled to 180 days of marketing exclusivity. Lupin Pharmaceuticals Inc. (LPI), the company's US subsidiary would commence marketing the products shortly.

Monodox® Capsules had annual U.S sales of US\$ 180.6 million (IMS MAT Dec, 2013) whereas Cipro® Oral Suspension had annual U.S sales of US\$ 8.6 million (IMS MAT Dec, 2013).

About Lupin Limited

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 the 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 revenues. 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.

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 more information, please contact -

Press Release



REUTERS: LUPIN.BO BLOOMBERG: LPC IN BSE: 500257 **NSE: LUPIN**

Shamsher Gorawara Head – Corporate Communications Ph: +91-22-66402531

 $\textbf{Email:} \underline{\textbf{shamshergorawara@lupinpharma.com}}$

or

Alpesh Dalal Head – M & A and Investor Relations Lupin Limited Ph: +91 98 20 023 511

Email: alpeshdlal@lupinpharma.com

<u>Safe Harbor Statement</u>
* Monodox** is a registered trademark owned by Pharmacia and Upjohn Company.
* CIPRO is a registered trademark of Bayer Aktiengesellschaft.