Press Release



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

Lupin Receives FDA Approval for New Drug Application for SUPRAX® Oral Suspension, 500 mg/5mL Approval to add to growing SUPRAX® Franchise

Mumbai, Baltimore, February 22, 2013: Pharma major, Lupin Ltd., announced today that its subsidiary, Lupin Pharmaceuticals Inc. (collectively, Lupin) has received approval for SUPRAX® (Cefixime) for Oral Suspension, 500 mg/5mL from the United States Food and Drugs Administration (FDA). Lupin expects to commence shipping the product in the near future.

The approval will expand Lupin's range of SUPRAX® dosage forms available to treat approved indications in appropriate patients. SUPRAX® is currently available as 100 mg/5ml and 200 mg/5ml suspensions; 400 mg tablets as well as chewable tablets 100 & 200 mg.

This new drug application provides for a new strength, 500mg/5mL, of SUPRAX (cefixime) for Oral Suspension for the treatment of otitis media, acute exacerbation of chronic bronchitis, uncomplicated urinary tract infections, uncomplicated gonorrhea (cervical/urethral) and pharyngitis/tonsillitis.

Commenting on the approval, Ms. Vinita Gupta, Group President, Lupin Limited & CEO, Lupin Pharmaceutical Inc. said "We are happy to receive this approval. The new dosage form will add to our growing SUPRAX franchise and gives health care providers and patients a new formulation to treat the indicated infections. The approval of SUPRAX for Oral Suspension is one more example of our ongoing commitment to serving our customers and addressing their needs."

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. 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 generics player in the US (5.1% 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 2012, Lupin's Consolidated Total Income and Profit after Tax were Rs. 70,972 million (USD 1.49 billion) and Rs.8,676 million (USD 182 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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