

<b>BSE : 500257</b>	NSE: Lupin	<b>REUTERS: LUPN.BO</b>	<b>BLOOMBERG: LPC IN</b>

## Lupin Announces U.S. FDA Approval of its First Oral Contraceptive

**Mumbai, September 20, 2011**: Pharma major, Lupin Ltd., announced today that its subsidiary, Lupin Pharmaceuticals Inc. (LPI) has been granted final approval by the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) to market a generic version of Watson's NOR-QD<sup>®</sup> tablets. Lupin will commence shipping its norethindrone tablets, USP 0.35 mg shortly.

NOR-QD<sup>®</sup> (norethindrone tablets, USP 0.35 mg) is a progestin-only oral contraceptive indicated for the prevention of pregnancy. Combined annual sales for NOR-QD<sup>®</sup> and its generic equivalents were approximately \$52 million for the twelve months ended June 2011 based on IMS Health sales data.

Commenting on the approval, Nilesh Gupta, Group President and Executive Director, Lupin Limited said, "This ANDA approval from the U.S. FDA marks Lupin's foray into the U.S. Oral Contraceptive market. We look forward to several more approvals and launches in the quarters and years to come."

## About Lupin Limited

Headquartered in Mumbai, India, Lupin Limited is an innovation led transnational pharmaceutical company producing a wide range of quality, affordable generic and branded formulations and APIs. The Company today has significant market share in Cardiovasculars, Diabetology, Asthma, Pediatrics, CNS, GI, Anti-Infectives and NSAIDs in addition holding global leadership positions in the Anti-TB and Cephalosporins space.

Today, Lupin is the 5th largest and fastest growing generics player in the US (by prescriptions), the only Asian company to achieve that distinction. The company is also the fastest growing top 10 pharmaceutical player in India, Japan and South Africa. (IMS Health)

For the financial year ended March 2011, Lupin's Consolidated Revenues and Profit after Tax were Rs.57,068 million (USD 1.28 Billion) and Rs. 8,626 million (USD 193 million) respectively. Please visit <u>http://www.lupinworld.com</u> for more information about Lupin Ltd.

Lupin Pharmaceuticals, Inc. is the U.S. wholly owned 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 under the U. S. Private Securities Litigation Reform Act of 1995:

This release contains forward-looking statements that involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. Many of these risks, uncertainties and other factors include failure of clinical trials, delays in development, registration and product approvals, changes in the competitive environment, increased government control over pricing, fluctuations in the capital and foreign exchange markets and the ability to maintain patent and other intellectual property protection. The information presented in this release represents management's expectations and intentions as of this date. Lupin expressly disavons any obligation to update the information presented in this release

\*NOR-QD® is a registered trademark of Watson Laboratories, Inc.