Lupin receives USFDA approval for cefotaxime sterile vials for injection_____

Mumbai, 25 September 2003: Lupin Ltd today announced that the U.S. Food and Drug Administration (USFDA) has approved the company's abbreviated new drug application (ANDA) for cefotaxime vials for injection 500 mg, 1g and 2g, the generic equivalent of Claforan® marketed by Abbott Laboratories, Inc.

This ANDA approval is the first injectable finished product approval for Lupin in the US market. Lupin is also the first Indian company to receive US FDA approval for an injectable finished product. This is also one of the few injectable plants approved outside the US and Europe.

At present, Lupin is supplying cefotaxime API to its alliance partner APP for the US market. Lupin had filed its own ANDA to overcome any constraints that the alliance partner may have in future. APP launched the product in the US in the third quarter of 2001 as the first generic and continues to be the sole generic on the market. The market size of cefotaxime is US $36.5 million (MAT June 2003) as per IMS.

Cefotaxime is a semi-synthetic, broad-spectrum cephalosporin antibiotic generally prescribed for infections of GI tract, lower respiratory tract infections, CNS (including ventriculitis and meningitis), surgical prophylaxis, gynecologic infections, intra-abdominal infections, septicemia and bacteremia.

The is the second ANDA approval for Lupin in Q2 FY2003-04. Lupin received FDA approval for cefuroxime axetil tablets in July 2003.

About Lupin

Headquartered in Mumbai, Lupin develops, manufactures and markets generic intermediates, active pharmaceutical ingredients and finished dosages. Lupin's revenue in FY2002-03 was Rs.11.2 billion on an equity base of Rs. 401 million.

Nine of Lupin's plants have been approved by the USFDA and two plants have been approved by the UKMCA.

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