

## Lupin files ANDAs for Ceftriaxone and Cefotaxime\_\_\_\_\_

- First US filings by the company in niche Cephalosporin molecules.
- Total current market size about \$750 million in the US.
- Believes it has first to file status for Ceftriaxone.

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Mumbai, April 16: Lupin Limited has recently filed 2 ANDAs -- Abbreviated New Drug Applications - with the USFDA for Ceftriaxone injection and Cefotaxime injection in the cephalosporins segment. The filings mark the company's entry into this segment in the US generics markets and the first step towards capturing a share of the market for niche cephalosporin molecules.

The first of the two filings is Ceftriaxone for injection in four dosage forms -- 250mg, 500mg, 1g, and 2g. Hoffman-La Roche Inc. holds the patent for Ceftriaxone (brand name Rocephin). The patent is due to expire in July 2005. Ceftriaxone is the single largest Cephalosporin with a global market of US\$1.3 billion out of the total Cephalosporin market of US\$9.85 billion.

Generally prescribed for urinary tract infections, lower respiratory tract infections, meningitis, skin and skin structure infections, surgical prophylaxis, intra-abdominal infections and pelvic inflammatory disease, Ceftriaxone dosage form's present market size is more than \$700 million in the US.

Lupin believes it is the first company to file an ANDA for this molecule.

Lupin's second ANDA filing is for Cefotaxime for injection for three dosage forms -- 500mg, 1g and 2g. The patent for Cefotaxime dosage form (brand name Claforan), which was held by Aventis, has expired. The current market size of Cefotaxime in the US is \$56 million (IMS 2000).

At present, Lupin is supplying Cefotaxime-API (active pharmaceutical ingredient) to its marketing alliance partner APP for the US markets. The company is in a near exclusive position in this market. As part of its mutually exclusive agreement with APP, Lupin has now filed its own ANDA to overcome any capacity constraints that the alliance may face in future. Cefotaxime is generally prescribed for infections of GU tract, lower respiratory tract infections, CNS (including ventriculitis and meningitis), surgical prophylaxis, gynecologic infections, intra-abdominal infections, septicemia and bacteremia.

'Over the last few years we have been following a twin strategy - increased R&D for NCE (new chemical entities) and NDDS (novel drug delivery systems) development, as well as actively scouting international opportunities in areas where we have core expertise such as cephalosporins and cardiovasculars. Towards this end we have created a new state-of-art R&D centre at Pune. These two ANDA filings are the result of this strategy,' said D B Gupta, Chairman and Managing Director, Lupin Limited.

A generic drug application is termed 'abbreviated' in that the application does not include pre-clinical (animal) and clinical (human) data to establish safety and effectiveness. The objective of an ANDA filing is to prove the bioequivalence of the generic drug with the original patented drug. The FDA checks include bioequivalence, chemical tests, toxicity, drug interactions, and inspection of facilities and packaging details.

### **About Lupin**

Promoted in 1968 by technocrat D B Gupta, Lupin Limited is among India's largest pharmaceutical companies. Its revenues in FY 2001 (April-March) were Rs.9.11 billion.

From its world-class facilities in Aurangabad and Tarapur (Maharashtra), Mandideep (Madhya Pradesh) and Ankleshwar (Gujarat), Lupin manufactures intermediates, bulk actives, formulations and phytomedicines.

Lupin is a global leader in the anti-TB segment; it is the world's largest manufacturer of Ethambutol and Rifampicin (through the complex fermentation process). Its Rifampicin plant is one of only three plants in the world approved by the USFDA.

Being the world's largest integrated manufacturer of cephalosporins, Lupin naturally has a strong presence in this segment. Other principle therapeutic areas: cardiovasculars and non-steroidal anti-inflammatory drugs (NSAIDs).

The company ranks 11th in the ORG MARG prescription audit. Seven of its products feature in the top 250 brands in India.

Lupin is among India's largest pharmaceutical exporters.

The company's R&D Park, in Pune city near Mumbai, conducts leading-edge research in generics, new chemical entities (NCEs) and phytomedicines. Lupin has a total of 66 patent filings and 70 DMFs (Drug Master Files).

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