NEWS RELEASE
11th February 2016, Hyderabad, India

Aurobindo Pharma receives USFDA Approval for Levofloxacin in Dextrose Injection

Aurobindo Pharma Limited is pleased to announce that the company has received final approval from the US Food & Drug Administration (USFDA) to manufacture and market Levofloxacin in 5% Dextrose Injection, 250 mg/50 mL (5 mg/mL), 500 mg/100 mL (5 mg/mL), and 750 mg/150 mL (5 mg/mL), single-use containers. The product is expected to be launched in Q1 FY16-17.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Levaquin® (Levaquin in 5 % Dextrose) by Janssen Pharmaceuticals, Inc.

Levofloxacin in Dextrose Injection is an Anti-Infective used in the treatment of bacterial infection in adults. The approved product has an estimated market size of US$ 46 million for the twelve months ending December 2015 according to IMS.

This is the 25th ANDA (including two tentative approvals) to be approved out of Unit IV formulation facility in Hyderabad, India used for manufacturing general injectable products. Aurobindo now has a total of 240 ANDA approvals (206 Final approvals including 10 from Aurolife Pharma LLC and 34 Tentative approvals) from USFDA.

About Aurobindo Pharma Limited:
Aurobindo Pharma Limited (www.aurobindo.com) (NSE: AUROPHARMA, BSE: 524804, Reuters: ARBN.NS, Bloomberg: ARBP:IN), headquartered at Hyderabad, India, manufactures generic pharmaceuticals and active pharmaceutical ingredients. The company's manufacturing facilities are approved by several leading regulatory agencies like US FDA, UK MHRA, Japan PMDA, WHO, Health Canada, MCC South Africa, ANVISA Brazil. The company's robust product portfolio is spread over 6 major therapeutic/product areas encompassing Antibiotics, Anti-Retrovirals, CVS, CNS, Gastroenterologicals, and Anti-Allergies, supported by an outstanding R&D set-up. The Company is marketing these products globally, in over 150 countries.

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