NEWS RELEASE
16th January 2016, Hyderabad, India

Aurobindo Pharma receives USFDA Approval for Tranexamic Acid 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 Tranexamic Acid Injection, (100 mg/mL) 1000 mg/10 mL single-dose vial. This product is expected to be launched by the end of Q4 FY15-16.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Cyklokapron® Injection, 100 mg/mL, of Pharmacia and Upjohn Company.

Tranexamic Acid Injection is used in the treatment of short-term control of bleeding in hemophiliacs, including dental extraction procedures. This product is in the WHOs list of essential medicines. The approved product has an estimated market size of US$ 50 million for the twelve months ending November 2015 according to IMS.

This is the 22nd ANDA (including two tentative approval) approved out of Unit IV formulation facility in Hyderabad, India used for manufacturing general injectable products. Aurobindo now has a total of 232 ANDA approvals (201 Final approvals including 10 from Aurolife Pharma LLC and 31 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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