NEWS RELEASE
27 December 2017, Hyderabad, India

Aurobindo Pharma receives USFDA Approval for Fondaparinux Sodium 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 Fondaparinux Sodium injection, 2.5 mg/0.5 mL, 5 mg/0.4 mL, 7.5 mg/0.6 mL, and 10 mg/0.8 mL single-dose prefilled syringes. The approved ANDA is a bioequivalent and therapeutically equivalent to the reference listed drug (RLD) product Arixtra® Injection of Mylan Ireland. The product will be launched in January 2018.

Fondaparinux Sodium injection is used to prevent deep vein thrombosis (DVT). The approved product has an estimated market size of US$ 73 million for the twelve months ending October 2017 according to IMS.

This is the 52nd ANDA (including 2 tentative approvals) to be approved out of Unit IV formulation facility in Hyderabad, India used for manufacturing general injectable & ophthalmic products. Aurobindo now has a total of 350 ANDA approvals (313 Final approvals including 17 from Aurolife Pharma LLC and 37 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 7 major therapeutic/product areas encompassing Antibiotics, Anti-Retrovirals, CVS, CNS, Gastroenterologicals, Anti-Allergies and Anti-Diabetics, supported by an outstanding R&D set-up. The Company is marketing these products globally, in over 150 countries.

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