

NEWS RELEASE

8 Aug 2016, Hyderabad, India

Aurobindo Pharma receives USFDA Approval for Linezolid 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 Linezolid Injection, 600 mg/300 mL (2 mg/mL). The product is expected to be launched by Q2 FY2016-17.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Zyvox® Injection, 600 mg/300 mL (2 mg/mL), of Pharmacia & Upjohn Company (Pharmacia).

Linezolid Injection is an anti-infective used to treat infections caused by susceptible Gram-positive bacteria in some specific conditions. The approved product has an estimated market size of US\$ 87 million for the twelve months ending June 2016 according to IMS.

This is the 36th ANDA (including 2 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 275 ANDA approvals (235 Final approvals including 13 from Aurolife Pharma LLC and 40 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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