

NEWS RELEASE

3<sup>rd</sup> February 2016, Hyderabad, India

**Aurobindo Pharma receives USFDA Approval for Isosulfan Blue 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 Isosulfan Blue Injection, 1% (50 mg/5 mL) single-dose vials. The product is expected to be launched in Q4 FY15-16.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Lymphazurin<sup>TM</sup> Injection, 1%, of Covidien.

Isosulfan Blue Injection under Cardio Vascular therapeutic group, is used in a lymphography procedure. Isosulfan Blue Injection upon subcutaneous administration, delineates the lymphatic vessels draining the region of injection. The approved product has an estimated market size of US\$ 57 million for the twelve months ending December 2015 according to IMS.

This is the 24<sup>th</sup> 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 237 ANDA approvals (205 Final approvals including 10 from Aurolife Pharma LLC and 32 Tentative approvals) from USFDA.

**About Aurobindo Pharma Limited:**

Aurobindo Pharma Limited ([www.aurobindo.com](http://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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