

NEWS RELEASE 30 July 2018, Hyderabad, India

## <u>Aurobindo Pharma receives USFDA Approval for Bivalirudin Injection</u>

Drug approved out of Unit IV facility

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 Bivalirudin injection, 250 mg/vial. The approved ANDA is a generic equivalent to the reference listed drug (RLD) product Angiomax® Injection of The Medicines Company.

The estimated market size Bivalirudin injection is US\$ 101 million for the twelve months ending May 2018 according to IQVIA. The product will be launched in September 2018.

Bivalirudin injection is indicated for use as an anticoagulant in patients:

- with unstable angina undergoing percutaneous transluminal coronary angioplasty
- undergoing percutaneous coronary intervention (PCI) with provisional use of glycoprotein IIb/IIIa inhibitor (GPI) as in the REPLACE-2 study
- with, or at risk of, heparin-induced thrombocytopenia (HIT) or heparin induced thrombocytopenia and thrombosis syndrome (HITTS), undergoing PCI

Bivalirudin is intended for use in these indications with aspirin.

This is the 53<sup>rd</sup> ANDA (including 1 tentative approval) 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 381 ANDA approvals (348 Final approvals including 17 from Aurolife Pharma LLC and 33 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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