

NEWS RELEASE 2<sup>nd</sup> February 2016, Hyderabad, India

## **Aurobindo Pharma receives USFDA Approval for Celecoxib Capsules**

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 Celecoxib Capsules, 50 mg, 100 mg, 200 mg, and 400 mg. This 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) Celebrex® Capsules, 50 mg, 100 mg, 200 mg, and 400 mg, of GD Searle, LLC.

Celecoxib Capsules is used in the treatment of pain and inflammation of osteoarthritis, rheumatoid arthritis, Juvenile Rheumatoid Arthritis (2 years and older) ankylosing spondylitis, acute pain in adults, primary dysmenorrhea. The approved product has an estimated market size of US\$ 976 million for the twelve months ending November 2015 according to IMS.

This is the 61<sup>st</sup> ANDA (including 11 tentative approvals) to be approved out of Unit VII formulation facility in Hyderabad, India for manufacturing Oral Non-Antibiotic products. Aurobindo now has a total of 235 ANDA approvals (203 Final approvals including 10 from Aurolife Pharma LLC and 32 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.

## For further information, please contact:

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# **AUROBINDO PHARMA LIMITED**

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