

NEWS RELEASE

20 July 2016, Hyderabad, India

**Aurobindo Pharma receives USFDA Approval for Rosuvastatin Calcium Tablets**

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 Rosuvastatin Calcium Tablets, 5 mg (base), 10 mg (base), 20 mg (base) and 40 mg (base). Aurobindo was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification, therefore, Aurobindo is eligible for 180 days of generic drug shared exclusivity. The product is launched in the US market.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) CRESTOR® (rosuvastatin calcium) Tablets 5 mg, 10 mg, 20 mg and 40 mg of IPR Pharmaceuticals Inc.

Rosuvastatin Calcium Tablets is an antihyperlipidemic to prevent cardiovascular disease. It is used to reduce elevated total-C, LDL-C, ApoB, non HDL-C, and TG levels and to increase HDL-C in patients with primary hypercholesterolemia and mixed dyslipidemia. The approved product has an estimated market size of US\$ 6.7 billion for the twelve months ending May 2016 according to IMS.

This is the 112<sup>th</sup> ANDA (including 19 tentative approvals) to be approved out of Unit III formulation facility in Hyderabad, India for manufacturing Oral Non-Antibiotic products. Aurobindo now has a total of 274 ANDA approvals (234 Final approvals including 13 from Aurolife Pharma LLC and 40 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 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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