10th July 2015

Aurobindo Pharma receives USFDA Approval for Flecainide Acetate 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 Flecainide Acetate Tablets USP 50 mg, 100 mg and 150 mg (ANDA 202821). Aurobindo will commence shipping shortly.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Tambocor® Tablets, 50 mg, 100 mg, 150 mg. Flecainide Acetate Tablets are an antiarrhythmic agent with an estimated market size of US$61 Million for the twelve months ending April 2015 according to IMS.

This is the 40th ANDA to be approved out of Unit VII formulation facility in Hyderabad, India for manufacturing Oral Non-betalactam products.

About Aurobindo Pharma Limited:

Aurobindo Pharma Limited (www.aurobindo.com), 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-Allergics, supported by an outstanding R&D set-up. The Company is marketing these products globally, in over 125 countries.

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