9th October 2015

Aurobindo Pharma receives USFDA Approval for Aripiprazole Tablets

Aurobindo Pharma Limited is pleased to announce that the company has received the final approval from the US Food & Drug Administration (USFDA) to manufacture and market Aripiprazole Tablets, 2mg, 5mg, 10mg, 15mg, 20mg and 30mg (ANDA 203908). The product is ready for launch.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Abilify® Tablets 2mg, 5mg, 10mg, 15mg, 20mg and 30mg of Otsuka Pharmaceutical Company, Ltd (Otsuka).

Aripiprazole Tablets are atypical antipsychotic indicated in the treatment symptoms of psychotic conditions such as schizophrenia and bipolar disorder (manic depression). The approved product has an estimated market size of US$7.3 Billion for the twelve months ending August 2015 according to IMS.

This is the 48th ANDA to be approved out of Unit VII formulation facility in Hyderabad, India for manufacturing Oral Non-Antibiotic products. Aurobindo now has a total of 215 ANDA approvals (187 Final approvals including 10 from Aurolife Pharma LLC and 28 Tentative approvals) from USFDA

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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