27th August 2015

Aurobindo Pharma receives USFDA Approval for Entecavir 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 Entecavir Tablets, 0.5mg and 1mg (ANDA 206217).

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Baraclude® Tablets, 0.5mg and 1mg, of Bristol-Myers Squibb.

Entecavir Tablets are indicated for treatment of chronic hepatitis B virus infection of the liver. The product has an estimated market size of US$294 Million for the twelve months ending June 2015 according to IMS.

This is the 44th 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 209 ANDA approvals (181 Final approvals including 9 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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