



28th June 2013

Aurobindo Pharma receives Tentative Approval for Efavirenz+Lamivudine+ Tenofovir Disoproxil Fumarate Tablets, 600mg/300mg/300mg (NDA)

Aurobindo Pharma Limited is pleased to announce that it has received the tentative approval to manufacture and market Efavirenz+Lamivudine+Tenofovir Disoproxil Fumarate Tablets, 600mg/300mg/300mg from the US Food & Drug Administration (USFDA).

The New Drug Application (NDA) 22-343 provides for the use of Efavirenz+Lamivudine+Tenofovir Disoproxil Fumarate Tablets, 600mg/300mg/300mg alone or in combination with other antiretrovirals for the treatment of HIV-1 infection in adults and adolescents aged more than 16 years of age and weighing atleast 40 kg.

This NDA was reviewed under the President's Emergency Plan for AIDS Relief (PEPFAR). The estimated ARV Access Market (Emerging Markets) for the product is USD120 million last year and expected to record strong growth in the coming year.

Aurobindo now has a total of 191 ANDA approvals (163 Final approvals including 4 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, 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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