3rd April 2013

Aurobindo Pharma receives tentative approval for Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate Tablets

Aurobindo Pharma Limited is pleased to announce that it is one of the first generics company to have received the tentative approval to manufacture and market its anti-AIDS combination drug Efavirenz / Emtricitabine and Tenofovir Disoproxil Fumarate Tablets, 600mg/200mg/300mg from the US Food & Drug Administration (USFDA).

Efavirenz / Emtricitabine and Tenofovir Disoproxil Fumarate Tablets, 600mg/200mg/300mg is the generic equivalent of Gilead Sciences Inc’s Atripla® Tablets 600mg/200mg/300mg and falls under the Anti-Retroviral (ARV) segment. It is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults. This ANDA was reviewed under the expedited provisions of the President’s Emergency Plan for AIDS relief (PEPFAR).

Aurobindo now has a total of 182 ANDA approvals (156 Final approvals including 2 from Aurolife Pharma LLC and 26 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.

For further information, please contact:

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