Aurobindo Pharma receives USFDA approval for Galantamine Tablets

30th March 2011

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 Galantamine Tablets USP 4mg, 8mg and 12mg

Galantamine Tablets USP 4mg, 8mg and 12mg is the generic version of Ortho McNeil Janssen Pharmaceutical, Inc's Razadyne® Tablets 4mg, 8mg and 12mg. The product falls under the neurological (CNS) therapeutic category and is indicated for the treatment of mild to moderate dementia of the Alzheimer's type. The product has a market size of approximately US$ 41 million for the twelve months ending September 2010 according to IMS and will be launched shortly.

Aurobindo now has a total of 133 ANDA approvals (101 Final approvals and 32 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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