Aurobindo Pharma receives tentative approval for Donepezil Hydrochloride Tablets from USFDA

Aurobindo Pharma Limited is pleased to announce that it has received the tentative approval for Donepezil Hydrochloride Tablets 5mg and 10mg (ANDA 90-056) from the US Food & Drug Administration (USFDA).

Donepezil Hydrochloride Tablets 5mg and 10mg is the generic equivalent to Aricept® Tablets 5mg and 10mg of Eisai Medical Research Inc. Donepezil Hydrochloride Tablets are indicated for the treatment of mild, moderate, and severe dementia of the Alzheimer's type and fall under the Central Nervous System (CNS) therapeutic segment. The product has a market size of approximately US$ 1.9 billion for the twelve months ending Dec 2008 according to Newport.

Aurobindo now has a total of 99 ANDA approvals (70 Final approvals and 29 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, TGA Australia. 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 100 countries.

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