Aurobindo Pharma receives USFDA approval for Ranitidine Syrup

2nd August 2010

Aurobindo Pharma Limited is pleased to announce that the company has received final approval from the US Food & Drug Administration (USFDA) for Ranitidine Syrup (Ranitidine Oral solution, USP) 15mg (base) /ml.

Ranitidine Hydrochloride Syrup USP 15mg (base) /ml is the generic equivalent of reference listed drug Zantac® Syrup, Oral 15mg (base) /ml of GlaxoSmithKline. Ranitidine Syrup falls under the Gastrointestinal (GI) therapeutic category and is indicated for treatment and maintenance therapy for active duodenal ulcer, benign gastric ulcer and erosive esophagitis. The product has a market size of approximately US$ 40 Million according to IMS and is ready for launch.

Aurobindo now has a total of 121 ANDA approvals (91 Final approvals and 30 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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