19th March 2015

Aurobindo Pharma receives USFDA Tentative Approval for Lacosamide Tablets

Aurobindo Pharma Limited is pleased to announce that US Food & Drug Administration (USFDA) has granted the tentative approval for Lacosamide Tablets 50mg, 100mg, 150mg and 200mg (ANDA 204994).

Lacosamide Tablets are the generic equivalent of USB Inc's Vimpat® Tablets and used in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older with a market size of approximately US$ 593 Million for the twelve months ending January 2015 according to IMS.

This ANDA contains a Paragraph IV certification and is currently under litigation in the United States District Court for the District of Delaware [UCB Inc, UCB Pharma GMBH Research Corporation Technologies Inc. and Harris FRC Corporation v. Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc, Civil Action No. 1:13-cv-01210-UNA].

Aurobindo (incl. Aurolife) now has a total of 193 ANDA approvals (165 Final approvals 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, Japan PMDA, 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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