4th April 2015

Aurobindo Pharma receives USFDA Approval for Sildenafil Injection

Aurobindo Pharma Limited is pleased to announce that the company has received final approvals from the US Food & Drug Administration (USFDA) to manufacture and market Sildenafil Injection, 10mg/12.5mL (0.8mg/mL) (ANDA 203988).

Sildenafil Injection 10mg/12.5mL (0.8mg/mL) is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD), Revatio® (sildenafil) Injection, 10 mg/12.5 mL (0.8 mg/mL), of Pfizer. Sildenafil Injection is indicated for the treatment of adult patients (≥ 18 years) with pulmonary arterial hypertension who are temporarily unable to take oral therapy, but are otherwise clinically and haemodynamically stable.

This is the 9th ANDA (represented by 7 product classes) to be approved out of Unit IV formulation facility in Hyderabad, India for manufacturing general injectable products and will be marketed and sold by Aurobindo's wholly owned subsidiary AuroMedics Pharma LLC

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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