



6<sup>th</sup> August 2012

## **Aurobindo Pharma receives final approvals for Montelukast Sodium Tablets and Chewable Tablets**

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 Montelukast Sodium Tablets 10mg (ANDA 202468) and Montelukast Sodium Chewable Tablets 4mg and 5mg (ANDA 202096). The products are ready for a first-day launch.

Montelukast Sodium Tablets 10mg and Chewable Tablets 4mg and 5mg are the generic equivalent of Merck & Co. Inc's Singulair® Tablets 10mg and Chewable Tablets 4mg and 5mg respectively.

Montelukast sodium is indicated for:

- \* Prophylaxis and chronic treatment of asthma in adults and pediatric patients 12 months of age and older
- \* Prevention of exercise-induced broncho-constriction in patients 15 years of age and older
- \*The relief of symptoms of allergic rhinitis (seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older, and perennial allergic rhinitis in adults and pediatric patients 6 months of age and older).

The annual sales of Montelukast Sodium Tablets 10mg is approximately US\$ 3.5Billion and that of Montelukast Sodium Chewable Tablets is US\$ 1.1Billion for the twelve months ending March 2012 according to IMS

The products have been approved out of Unit VII (SEZ) formulations facility in Hyderabad, India

Aurobindo now has a total of 157 ANDA approvals (131 Final approvals including 1 from Aurolife Pharma LLC and 26 Tentative approvals) from USFDA

### **About Aurobindo Pharma Limited:**

Aurobindo Pharma Limited ([www.aurobindo.com](http://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.

### **For further information, please contact:**

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