Received 46th ANDA approval from US FDA for Terbinafine HCL Tablets

Aurobindo Pharma Limited is pleased to announce that the Company has received approval from the US FDA for Terbinafine Hydrochloride Tablets 250 mg. This approval is received on the first day after the expiry of the relevant patent.

Terbinafine Hydrochloride Tablets 250 mg are the generic equivalent of Novartis anti fungal Lamisil® tablets. The brand product has annual sales of approximately USD 654 million in the US.

AUROBINDO PHARMA LTD

Aurobindo Pharma Limited, headquartered at Hyderabad, India, manufactures generic pharmaceuticals and active pharmaceutical ingredients.

The company has received approvals for most of the targeted API and formulation facilities from leading regulatory agencies like US FDA, UK MHRA, WHO, Health Canada, MCC South Africa.

The company's robust product portfolio is spread over 6 major therapeutic/product areas encompassing Antibiotics, Anti-Retrovirals, CVS, CNS, Gastroenterologicals, and Anti-Allergics.

The formulation portfolio is built on six technology platforms such as immediate release generics, SR/CR generics, and Orally disintegrating/Mouth dissolving generics, Combination products, Sterile/Lyophilized generics and Liquids/Dry syrups.

Aurobindo has filed over 110 DMFs and 90 ANDAs for the USA market alone in addition to filings in other countries. The pace of filings is matched by rapid product approvals from various markets. Till date Aurobindo received 45 ANDA approvals (both final and tentative) from US alone. Aurobindo operates in over 100 countries and markets over 180 APIs and 250 formulations.