

Lupin gets DCGI approval to conduct Phase III clinical trials for Migraine NCE

BSE : 500257	NSE: Lupin	REUTERS: LUPN.BO	BLOOMBERG: LPC IN
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Mumbai, 7 December 2006: Lupin Ltd. announced that it has got approval from Drugs Controller General (India) (DCGI) to conduct Phase-III Clinical Trials for its Anti-Migraine compound LLL-2011 (Amigra).

The botanical drug product LLL-2011 is formulated as a nasal spray for use in the prophylaxis of migraine. Phase II clinical trials evaluated the nasal spray in different doses and the study was conducted as a multicentric, placebo-controlled, randomized, double blind, parallel group study.

The results of the study showed that LLL-2011 nasal spray is effective in the prophylactic treatment of migraine. It produced significant reduction in frequency of migraine attacks and on the Total Pain Index (TPI) of migraine in comparison to levels observed prior to treatment or levels in the placebo arm. The safety evaluation demonstrated that it was very safe and well tolerated. The company intends to begin Phase-III clinical trials in at least 10 centres across the nation. The total market for Migraine is estimated to be more than US\$ 2 billion.

Commenting on the approval, Lupin Ltd. Chairman, Dr. Desh Bandhu Gupta stated, “We are very excited with the approval and look forward to taking LLL-2011 through Phase III clinical trials and bring it to the market. This is a very important product for a highly unmet need and we look forward to addressing it effectively and safely”.

The Company also has three other New Chemical Entities in various stages of Clinical trials.

About Lupin

Headquartered in Mumbai, Lupin Ltd. is a leading pharmaceutical company with strong research focus. It has a programme for developing New Chemical Entities. The Company has state-of-the-art R&D center in Pune. The Company is a leading global player in Anti-TB, Cephalosporins (anti-infectives) and Cardiovascular drugs (prils and statins) and has a notable presence in the areas of diabetology, NSAIDS and Asthma.

For the half-year ended September 2006, the Company’s Revenues and Profit after Tax were Rs.9,917 million (US\$ 220 million) and Rs.1,090 million (US\$ 24 million) respectively.

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