

Lupin Receives Approval for Acotiamide Tablets to Treat Functional Dyspepsia

First-in-class product for the Indian market

Mumbai, August 22, 2016: Pharmaceutical Major Lupin Limited (Lupin) announced today that it has received approval for Acotiamide 100 mg Tablets from the Central Drugs Standard Control Organisation (CDSCO). Lupin shall commence promoting the product in India shortly.

Acotiamide is a first-in-class novel drug to be introduced into the Indian Pharmaceutical Market (IPM) which could benefit millions of patients suffering from Dyspepsia or Indigestion, amongst the most common stomach complaints encountered in clinical practice. The molecule is a 'Prokinetic' agent - a type of drug which enhances gastrointestinal motility. Acotiamide enhances gastric accommodation and gastric emptying, the two factors which have been implicated in the cause of functional dyspepsia. Acotiamide is approved by PMDA Japan and is actively marketed in Japan.

The current market for plain Gastrointestinal (GI) prokinetics and combinations is estimated to be around INR 2640 crores growing at 14%. The overall GI market is estimated at INR 11,438 crores which is growing at 13%. (IMS MAT June 2016)

According to gastroenterologists "a large number of patients often complain of a common condition that their stomach seems to be overfilled soon after they commence having their meals. This feeling results in the patient being unable to even finish their normal meals; a symptom referred to as early satiety. Some other patients describe the symptom as an unpleasant sensation like prolonged presence of food in the stomach (post meal fullness and discomfort) resulting in excessive bloating and belching. Acotiamide aims to address these common symptoms of dyspepsia (indigestion)." Acotiamide is approved for the treatment of post meal fullness, bloating and early satiety in functional dyspepsia by the CDSCO (India).

Mr. Naresh Gupta, President, Lupin Limited said "We have a rich legacy of having introduced novel treatments to address unmet medical needs in the country. I am sure that the approval of Acotiamide would go a long way in addressing an otherwise common but unmet medical need for a safe and effective drug for the management of dyspepsia."

About Lupin Limited

Lupin is an innovation led transnational pharmaceutical company producing and developing a wide range of branded & generic formulations, biotechnology products and APIs globally. The Company is a significant player in the Cardiovascular, Diabetology, Asthma, Pediatric, CNS, GI, Anti-Infective and NSAID space and holds global leadership position in the Anti-TB segment.

Lupin is the 5th largest generics player in the US (5.51% generic market share by prescriptions – IMS Health, National Prescription Audit, MAT March 2016) and the 2nd largest Indian pharmaceutical company by market capitalization. The Company is also the 9th largest generic pharmaceutical player in Japan and the 4th largest generic pharmaceutical company in South Africa (IMS Health, March 2016).

Press Release



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For the financial year ended 31st March, 2016, Lupin's Consolidated sales and Net profit stood at Rs. 136,539 million (USD 2.09 billion) and Rs. 22,607 million (USD 345 million) respectively. Please visit <http://www.lupin.com> for more information. You could also follow us on Twitter – www.twitter.com/lupinlimited

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