Natco Pharma Limited

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NATCO announces USFDA Tentative Approval for Armodafinil 50mg, 150mg, and 250mg Tablets

Hyderabad, India, October 21st, 2014

Natco Pharma Limited **(NSE: NATCOPHARM, BSE: 524816)** announced today that its marketing partner in the USA, Breckenridge Pharmaceutical, Inc., has received a **tentative approval** from the United States Food & Drug Administration (USFDA) for Armodafinil 50mg, 150mg, and 250mg Tablets.

Breckenridge filed the Abbreviated New Drug Application (ANDA) with a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use and sale of its generic to Nuvigil® prior to expiration of the listed patents. Natco and Breckenridge have entered into a settlement regarding the ANDA with Cephalon, the terms of which are confidential. Cephalon has granted Natco and Breckenridge a license to market generic versions of the 50mg, 100 mg, 150mg, 200 mg and 250mg strengths of Nuvigil®, beginning 180-days after the initial launch of these strengths.

Cephalon (acquired by Teva in 2011) sells Armodafinil 50mg, 150mg, and 250mg Tablets under Brand name Nuvigil® in the USA market. Nuvigil® is a wakefulness promoting agent for oral administration. The market size of Nuvigil® in the USA is approximately US $457 Million for twelve months ending August 2014, according to IMS Health.

Forwarded for favour of publication
For NATCO Pharma Limited

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