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Lupin Receives Tentative FDA Approvals for Generic Nuvigil® Tablets and Generic Oracea® Capsules

Mumbai, Baltimore, July 31, 2013: Pharma Major Lupin Limited announced today that its U.S. subsidiary, Lupin Pharmaceuticals, Inc. (LPI) has received tentative approval for its Armodafinil Tablets, 50 mg, 100 mg, 150 mg, 200 mg and 250 mg strengths **as well as** another tentative approval for its Doxycycline Capsules, 40 mg (30 mg Immediate-release and 10 mg Delayed-release) from the United States Food and Drugs Administration (FDA).

Lupin's Armodafinil Tablets are the AB-rated generic equivalent of Cephalon Inc's Nuvigil® tablets 50 mg, 100 mg, 150 mg, 200 mg and 250 mg strengths. Armodafinil Tablet is indicated to improve wakefulness in adult patients with excessive sleepiness associated with treated obstructive sleep apnea (OSA), narcolepsy, or shift work disorder.

Nuvigil® tablets, 50 mg, 100 mg, 150 mg, 200 mg and 250 mg had U.S sales of approximately **USD 420 million**, for the twelve months ending March, 2013 (IMS Health data).

Lupin's Doxycycline Capsules is the AB-rated generic equivalent of Galderma Laboratories Oracea® Capsules, 40 mg. Doxycycline Capsule is indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients.

Oracea® Capsules had annual U.S sales of approximately **USD 319 million** for the twelve months ending March, 2013 (IMS Health data).

About Lupin Limited

Headquartered in Mumbai, Lupin is an innovation led transnational pharmaceutical company producing and developing a wide range of branded and generic formulations 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 positions in the Anti-TB and Cephalosporin segment.

Lupin is the 5th largest and fastest growing top 5 generics player in the US (5.3% market share by prescriptions, IMS Health) and the 3rd largest Indian pharmaceutical company by sales. The Company is also the fastest growing top 10 generic pharmaceutical players in Japan and South Africa (IMS).

For the financial year ended March 2013, Lupin's Consolidated turnover and Profit after Tax were Rs. 94,616 million (USD 1.74 billion) and Rs. 13,142 million (USD 242 million) respectively. Please visit <http://www.lupinworld.com> for more information.

Lupin Pharmaceuticals, Inc. is the wholly owned U.S. subsidiary of Lupin Limited. Headquartered in Baltimore, Maryland, Lupin Pharmaceuticals, Inc. is dedicated to delivering high-quality, affordable generic medicines and branded formulations trusted by healthcare professionals and patients across geographies. For more information, visit <http://www.lupinpharmaceuticals.com>

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Press Release



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Safe Harbor Statement

**Nuvigil tablets, 50 mg, 100 mg, 150 mg, 200 mg and 250 mg are registered copyright of Cephalon Inc.*

*** Oracea Capsules 40 mg is a registered copyright of Galderma Laboratories, L.P. United States*