



## **Lupin Receives FDA Approval for Generic Ambien CR® Extended-release Tablets**

**Mumbai, Baltimore, September 16, 2013:** Pharma major, Lupin Limited (Lupin), announced today that it has received final approval for its Zolpidem Tartrate Extended-release tablets USP, 6.25 mg and 12.5 mg from the United States Food and Drugs Administration (FDA) to market a generic version of Sanofi Aventis, U.S, LLC's (Sanofi) Ambien CR® Extended-release tablets, 6.25 mg and 12.5 mg. Lupin's wholly owned US subsidiary Lupin Pharmaceuticals Inc. (LPI) shall commence marketing the product shortly.

Lupin's Zolpidem CR tablets 6.25 mg & 12.5 mg is the AB rated generic equivalent of Sanofi's Ambien CR® Extended-release tablets, 6.25 mg and 12.5 mg and is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

Sanofi's Ambien CR® Extended-release tablets had annual U.S sales of approximately US\$ 366 million (IMS MAT Mar 2013).

### **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

\* *Ambien CR<sup>®</sup> is the registered trademark of Sanofi Aventis, U.S, LLC*