

Lupin Receives FDA Approval for Generic Ortho-Cyclen® 28 Tablets

Mumbai, Baltimore, November 1, 2016: Pharma Major Lupin Limited (Lupin) announced today that it has received final approval for Norgestimate and Ethinyl Estradiol Tablets USP, 0.25 mg/0.035 mg from the United States Food and Drug Administration (FDA) to market a generic version of Janssen Pharmaceuticals, Inc.'s Ortho-Cyclen® 28 Tablets (Norgestimate/Ethinyl Estradiol). The approved product will be manufactured at Lupin's Pithampur facility.

Lupin's Norgestimate and Ethinyl Estradiol Tablets USP, 0.25 mg/0.035 mg are the AB rated generic equivalent of Janssen Pharmaceuticals, Inc.'s Ortho-Cyclen® 28 Tablets (Norgestimate/Ethinyl Estradiol). It is indicated for use by females of reproductive potential to prevent pregnancy.

Ortho-Cyclen® Tablets had US sales of USD 178.2 million (IMS MAT June 2016).

About Lupin Limited

Lupin is an innovation led transnational pharmaceutical company developing and delivering 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 and the 7th largest generics pharmaceutical company by market capitalization and sales globally (June 30th, 2016, Bloomberg). The Company is the 5th largest pharmaceutical player in the US by prescriptions (4.68% market share – IMS Health, National Prescription Audit, March 2016); the 3rd largest Indian pharmaceutical company by revenues; the 6th largest generic pharmaceutical player in Japan and the 4th largest generic pharmaceutical company in South Africa (IMS Health, March 2016).

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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Press Release



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Ortho-Cyclen® is the registered trademark of Johnson & Johnson Corporation.