

Lupin Receives FDA Approval for Generic Femhrt® Tablets

Mumbai, Baltimore, December 28, 2015: Pharma Major Lupin Limited (Lupin) has received final approval for its Fyavolv™ Tablets (Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 0.5 mg/0.0025 mg and 1 mg/0.005 mg) from the United States Food and Drug Administration (FDA) to market a generic version of Warner Chilcott's Femhrt® Tablets (Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 0.5 mg/0.0025 mg and 1 mg/0.005 mg). Lupin's US subsidiary, Lupin Pharmaceuticals Inc. shall commence promoting the product in the US shortly.

Lupin's Fyavolv™ Tablets (Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 0.5 mg/0.0025 mg and 1 mg/0.005 mg) are the AB rated generic equivalent of Warner Chilcott's Femhrt® Tablets (Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 0.5 mg/0.0025 mg and 1 mg/0.005 mg). It is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause and prevention of postmenopausal osteoporosis.

Femhrt® had US sales of USD 39.9 million (IMS MAT September 2015).

About Lupin Limited

Headquartered in Mumbai, 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 positions in the Anti-TB and Cephalosporin segment.

Lupin is the 6th largest generic pharmaceutical player in the US (5.5% market share by prescriptions, IMS Health) and the 3rd largest Indian pharmaceutical company by sales globally. The Company is also the fastest growing top 10 generic pharmaceutical players in Japan (ranked 8th) and South Africa (ranked 4th – IMS Health). For the financial year ended 31st March 2015, Lupin's Consolidated turnover and Profit after Tax were Rs. 125,997 million (USD 2.06 billion) and Rs. 24,032 million (USD 393 million) respectively.

About Lupin Pharmaceuticals Inc. (LPI)

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 on Lupin Limited, please visit <http://www.lupin.com>. You could also follow us on Twitter – www.twitter.com/lupinlimited

CIN: L24100MH1983PLC029442 Registered Office: 159, C.S.T. Road, Kalina, Santacruz (East), Mumbai - 400 098.

For further information or queries, please contact:

Shamsher Gorawara

Head – Corporate Communications

Ph: +91-98 20 338 555

Email: shamshergorawara@lupin.com

Press Release



BSE: 500257

NSE: LUPIN

REUTERS: LUPIN.BO

BLOOMBERG: LPC IN

Or

Alpesh Dalal
Head – M & A and Investor Relations
Lupin Limited
Ph: +91 98 20 023 511
Email: alpeshdalal@lupin.com

*[*Safe Harbor Statement](#)*

Femhrt® is the registered trademark of Warner Chilcott.