

Press Release

For Immediate Release

## Glenmark receives final ANDA approval for Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 0.5 mg/2.5 mcg and 1 mg/5 mcg

**Mumbai, India, April 7, 2015** Glenmark Generics Inc. USA, a subsidiary of Glenmark Generics Limited has been granted final abbreviated new drug approval (ANDA) from the United States Food and Drug Administration (US FDA) for Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 0.5 mg/2.5 mcg and 1 mg/5 mcg. Glenmark will commence distribution of the product immediately.

Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 0.5 mg/2.5 mcg and 1 mg/5 mcg are Glenmark's generic version of Warner Chilcott's FemHRT®. Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 0.5 mg/2.5 mcg and 1 mg/5 mcg are indicated for the treatment of moderate to severe vasomotor symptoms due to menopause and for the prevention of postmenopausal osteoporosis in women at significant risk of osteoporosis. For the 12 month period ending February 2015, the FemHRT® market garnered annual sales of USD 38.6 Million according to IMS Health.

Glenmark's current portfolio consists of 96 products authorized for distribution in the U.S. marketplace and 69 ANDA's pending approval with the US FDA. In addition to these internal filings, GGI continues to identify and explore external development partnerships to supplement and accelerate the growth of the existing pipeline and portfolio.

### **About Glenmark Generics Limited**

Glenmark Generics Limited (GGL) is a subsidiary of Glenmark Pharmaceuticals Limited (Glenmark) and aims to be a global integrated Generic and API leader. GGL has an established presence in North America and developing an EU presence. It primarily sells its FDF products in the United States ("US") and the European Union ("EU"), as well as its oncology FDF products in South America. The Company supplies APIs to customers in approximately 80 countries, including the US, various countries in the EU, South America and India.

**Note:** "The Hon'ble Bombay High Court passed an order approving the amalgamation of Glenmark Generics Limited with Glenmark Pharmaceuticals Ltd. We are currently in the process of complying with further directions of the said order."

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