

Press Release For Immediate Release

# Glenmark Pharmaceuticals receives ANDA approval for Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.02 mg

**Mumbai, India, January 21, 2016:** Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted final approval by the United States Food & Drug Administration (U.S. FDA) for Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.02 mg, the generic version of Loestrin® 21 1/20 Tablets of Warner Chilcott Company, LLC.

### **WARNING:**

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

According to IMS Health sales data for the 12 month period ending November 2015, the Loestrin® 21 1/20 Tablets market<sup>1</sup> achieved annual sales of approximately \$56.8 million\*.

Glenmark's current portfolio consists of 106 products authorized for distribution in the U.S. marketplace and 62 ANDA's pending approval with the U.S. FDA. In addition to these internal filings, Glenmark continues to identify and explore external development partnerships to supplement and accelerate the growth of its existing pipeline and portfolio.

All brand names and trademarks are the property of their respective owners. 1 Market includes brand and all available therapeutic equivalents

\*IMS Health National Sales Perspectives: Retail & Non-Retail, November 2015

## Glenmark Pharmaceuticals Ltd.



#### **About Glenmark Pharmaceuticals Ltd:**

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical company headquartered at Mumbai, India. It is ranked among the top 80 Pharma & Biotech companies of the world in terms of revenues (SCRIP 100 Rankings published in the year 2016). Glenmark is a leading player in the discovery of new molecules both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has several molecules in various stages of clinical development and is primarily focused in the areas of Inflammation [asthma/COPD, rheumatoid arthritis etc.] and Pain [neuropathic pain and inflammatory pain]. The company has a significant presence in branded generics markets across emerging economies including India. GPL along with its subsidiary has 16 manufacturing facilities in five countries and has six R&D centers.

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