**Press Release** **For Immediate Release**

# Glenmark Pharmaceuticals receives tentative ANDA approval for Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.01 mg, Ethinyl Estradiol Tablets USP, 0.01 mg and Ferrous Fumarate Tablets, 75 mg

**Mumbai, India; April 26, 2016**: Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted tentative approval by the United States Food & Drug Administration (U.S. FDA) for Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.01 mg, Ethinyl Estradiol Tablets USP, 0.01 mg and Ferrous Fumarate Tablets, 75 mg, the generic version of Lo Loestrin® Fe (norethindrone acetate and ethinyl estradiol, ethinyl estradiol and ferrous fumarate) Tablets of Allergan Pharms Intl.

**WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS**

**Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptives (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs should not be used by women who are over 35 years of age and smoke.**

Glenmark will market this product upon receiving final approval of its Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1 mg/0.01 mg, Ethinyl Estradiol Tablets USP, 0.01 mg and Ferrous Fumarate Tablets, 75 mg ANDA. The patent listed in the Orange Book for Lo Loestrin® Fe (norethindrone acetate and ethinyl estradiol, ethinyl estradiol and ferrous fumarate) Tablets is scheduled to expire on February 2, 2029.

According to IMS Health sales data for the 12 month period ending February 2016, the Lo Loestrin® Fe market1 achieved annual sales of approximately $ 432.2 million*.

Glenmark's current portfolio consists of 112 products authorized for distribution in the U.S. marketplace and 57 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, February 2016

***About Glenmark Pharmaceuticals Ltd.:***

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical organization headquartered at Mumbai, India. It is ranked among the top 80 Pharma & Biotech companies of the world in terms of revenue *(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 the branded generics markets across emerging economies including India. GPL along with its subsidiary has 16 manufacturing facilities across five countries and has six R&D centers. The Generics business of Glenmark services the requirements of the US and Western European markets. The API business sells its products in over 80 countries, including the US, various countries in the EU, South America and India.

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