Glenmark Pharmaceuticals receives ANDA approval for Levonorgestrel and Ethinyl Estradiol Tablets USP, 0.15 mg/0.03 mg

Mumbai, June 15, 2015 – Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted final approval by the United States Food & Drug Administration (U.S. FDA) for the extended-cycle oral contraceptive, Levonorgestrel/Ethinyl Estradiol Tablets USP, 0.15 mg/0.03 mg, the AB-rated generic version of Seasonale® by Teva Women's Health.

Seasonale® is indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception. According to IMS Health sales data for the 12 month period ending April 2015, the Seasonale® market[1] achieved annual sales of approximately $53.7 million*.

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.

Today's approval marks Glenmark's 12th oral contraceptive and 2nd extended-cycle oral contraceptive authorized for distribution by the U.S. FDA. Glenmark plans to commence shipping of Levonorgestrel/Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg immediately.

Glenmark's current portfolio consists of 99 products authorized for distribution in the U.S. marketplace and 66 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.

Important Safety Information:

Use of levonorgestrel and ethinyl estradiol tablets provides women with more hormonal exposure on a yearly basis than conventional monthly oral contraceptives containing similar strength synthetic estrogens and progestins (an additional 9 weeks per year). The convenience of fewer planned menses (4 per year instead of 13 per year) should be weighed against the inconvenience of increased intermenstrual bleeding and/or spotting.

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, April 2015

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 2014). 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 14 manufacturing facilities in four countries and has six R&D centers.

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