

Press Release

For Immediate Release

## **Glenmark Pharmaceuticals receives ANDA approval for Raloxifene Hydrochloride Tablets USP, 60 mg**

**Mumbai, March 23, 2016:** Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted final approval by the United States Food & Drug Administration (U.S. FDA) for Raloxifene Hydrochloride Tablets USP, 60 mg, the therapeutic equivalent to the reference listed drug product, Evista® Tablets, 60 mg, of Eli Lilly and Company.

### **WARNING: INCREASED RISK OF VENOUS THROMBOEMBOLISM AND DEATH FROM STROKE**

- Increased risk of deep vein thrombosis and pulmonary embolism have been reported with raloxifene hydrochloride. Women with active or past history of venous thromboembolism should not take raloxifene hydrochloride.
- Increased risk of death due to stroke occurred in a trial in postmenopausal women with documented coronary heart disease or at increased risk for major coronary events. Consider risk-benefit balance in women at risk for stroke.

According to IMS Health sales data for the 12 month period ending January 2016, the Evista® Market<sup>1</sup> achieved annual sales of approximately \$336.5 million\*.

Glenmark's current portfolio consists of 109 products authorized for distribution in the U.S. marketplace and 60 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.

<sup>1</sup>Market includes brand and all available therapeutic equivalents

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