

Press Release For Immediate Release

Glenmark Pharmaceuticals receives ANDA approval for HAILEY<sup>TM</sup> 1.5/30 (Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1.5 mg/30 mcg) and HAILEY<sup>TM</sup> Fe 1.5/30 (Norethindrone Acetate and Ethinyl Estradiol Tablets, USP and Ferrous Fumarate Tablets, 1.5 mg/30 mcg)

*Mumbai, India; June 06, 2018:* Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted final approval by the United States Food & Drug Administration (U.S. FDA) for HAILEY<sup>TM</sup> 1.5/30 (Norethindrone Acetate and Ethinyl Estradiol Tablets USP, 1.5 mg/30 mcg), the generic version of Loestrin<sup>®1</sup> 21 1.5/30 Tablets, of Allergan Pharmaceuticals International Limited (Allergan) and for HAILEY<sup>TM</sup> Fe 1.5/30 (Norethindrone Acetate and Ethinyl Estradiol Tablets, USP and Ferrous Fumarate Tablets, 1.5 mg/30 mcg), the generic version of Loestrin<sup>®</sup> Fe 1.5/30, also of Allergan.

According to IQVIA<sup>™</sup> sales data for the 12 month period ending April 2018, the Loestrin<sup>®</sup> 21 1.5/30 Tablets market<sup>2</sup> achieved annual sales of approximately \$24.2 million\* and the Loestrin<sup>®</sup> Fe 1.5/30 market achieved annual sales of approximately \$41.3 million.

Glenmark's current portfolio consists of 137 products authorized for distribution in the U.S. marketplace and 61 ANDAs 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.

<sup>1</sup>All brand names and trademarks are the property of their respective owners.

<sup>&</sup>lt;sup>2</sup>Market includes brand and all available therapeutic equivalents

<sup>\*</sup>IQVIA™ National Sales Perspectives: Retail & Non-Retail, April 2018

## Glenmark Pharmaceuticals Ltd.



## **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 75 Pharma & Biotech companies of the world in terms of revenue (SCRIP 100 Rankings published in the year 2017). 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 oncology, dermatology and respiratory.

The company has a significant presence in the branded generics markets across emerging economies including India. Glenmark along with its subsidiary has 17 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.

## For further information, please contact:

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