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

# Glenmark Pharmaceuticals receives tentative ANDA approval for Azelaic Acid Gel, 15%

**Mumbai; February 17, 2016:** Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted tentative approval by the United States Food & Drug Administration (U.S. FDA) for its Azelaic Acid Gel, 15%, the generic version of Finacea® Topical Gel, 15% of Bayer Healthcare. Glenmark will market this product upon receiving final approval of its Azelaic Acid Gel, 15% ANDA. The patent listed in the Orange Book for Finacea® Topical Gel, 15% is scheduled to expire on November 18, 2018.

According to IMS Health sales data for the 12 month period ending December 2015, the Finacea® market achieved annual sales of approximately $128.0 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, December 2015

**About Glenmark**

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 2015). 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 four countries and has six R&D centers. The Generics business of Glenmark services the requirements of the US and Western Europe

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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