

Press Release

For Immediate Release

## **Glenmark Pharmaceuticals receives tentative ANDA approval for Topiramate Extended-Release Capsules, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg**

**Mumbai, India, January 24, 2019:** Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted tentative approval by the United States Food & Drug Administration (U.S. FDA) for Topiramate Extended-Release Capsules, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg, a generic version of QUDEXY®<sup>1</sup> XR Extended-Release Capsules, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg, of Upsher-Smith Laboratories, LLC.

According to IQVIA™ sales data for the 12 month period ending November 2018, the QUDEXY® XR Extended-Release Capsules, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg market<sup>2</sup> achieved annual sales of approximately \$84.0 million\*.

Glenmark's current portfolio consists of 148 products authorized for distribution in the U.S. marketplace and 54 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.

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

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

\*IQVIA™ National Sales Perspectives: Retail & Non-Retail, November 2018

--End--

### **About Glenmark Pharmaceuticals**

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical organization. It is ranked among the top 75 Pharma & Biotech companies of the world in terms of revenue (SCRIP 100 Rankings published in the year 2018). 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 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 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.

### ***For further information, please contact:***

Isha Trivedi

Glenmark, Mumbai, India

Tel: +91 22 4018 9801

Email: [corpcomm@glenmarkpharma.com](mailto:corpcomm@glenmarkpharma.com)