

Press Release

For Immediate Dissemination

## Glenmark Pharmaceuticals receives tentative ANDA approval for Lacosamide Tablets, 50 mg, 100 mg, 150 mg and 200 mg

Mumbai, October 30, 2015: Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted tentative approval by the United States Food & Drug Administration (U.S. FDA) for its Lacosamide Tablets, 50 mg, 100 mg, 150 mg and 200 mg, the generic version of Vimpat® Tablets, 50 mg, 100 mg, 150 mg and 200 mg of UCB, Inc. Glenmark will market this product upon receiving final approval of its Lacosamide Tablets, 50 mg, 100 mg, 150 mg and 200 mg ANDA. The patent listed in the Orange Book for Vimpat® Tablets, 50 mg, 100 mg, 150 mg and 200 mg is scheduled to expire on March 17, 2022.

According to IMS Health sales data for the 12 month period ending September 2015, the Vimpat® market achieved annual sales of approximately \$691.0 million.

Glenmark's current portfolio consists of 102 products authorized for distribution in the U.S. marketplace and 64 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.

## **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 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].

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

<sup>\*</sup>IMS Health National Sales Perspectives: Retail & Non-Retail, September 2015

## Glenmark Pharmaceuticals Ltd.



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. 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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