Glenmark Pharmaceuticals Receives Tentative ANDA Approval For Solifenacin Succinate Tablets, 5 mg and 10 mg

MUMBAI, India; June 22, 2017: Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted tentative approval by the United States Food & Drug Administration (U.S. FDA) for Solifenacin Succinate Tablets, 5 mg and 10 mg, the generic version of Vesicare® Tablets, 5 mg and 10 mg of Astellas Pharma US Inc.

According to IMS Health sales data for the 12 month period ending April 2017, the Vesicare® Tablets, 5 mg and 10 mg market achieved annual sales of approximately $1.1 billion.

Glenmark’s current portfolio consists of 117 products authorized for distribution in the U.S. marketplace and 68 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
2 IMS National Sales Perspectives: Retail & Non-Retail, April 2017
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.

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