Glenmark Pharmaceuticals Ltd.

Press Release



For Immediate Release

Glenmark Pharmaceuticals receives ANDA approval for Potassium Chloride Extended-Release Tablets USP, 10 mEq (750 mg) and 20 mEq (1500 mg)

Mumbai, India; July 27, 2016: Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted final approval by the United States Food & Drug Administration (U.S. FDA) for Potassium Chloride Extended-Release Tablets USP, 10 mEq (750 mg) and 20 mEq (1500 mg), the generic version of K-Dur (Potassium Chloride) Extended-Release Tablets, 10 and 20 mEq, of Merck Sharp and Dohme Corp (which is no longer being marketed in the United States).

According to IMS Health sales data for the 12 month period ending May 2016, the K-Dur (Potassium Chloride) Extended-Release Tablets, 10 and 20 mEq market¹ achieved annual sales of approximately \$283.2 million*.

Glenmark's current portfolio consists of 117 products authorized for distribution in the U.S. marketplace and 61 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. ¹Market includes brand and all available therapeutic equivalents *IMS Health National Sales Perspectives: Retail & Non-Retail, May 2016



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 80 Pharma & Biotech companies of the world in terms of revenue (*SCRIP 100 Rankings published in the year 2016*). 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 the branded generics markets across emerging economies including India. GPL along with its subsidiary has 17 manufacturing facilities across five countries and has five 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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