

Press Release

For Immediate Release

Glenmark Pharmaceuticals receives ANDA approval for Rufinamide Tablets USP, 200 mg and 400 mg

Mumbai, India; May 19, 2016: Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted final approval by the United States Food & Drug Administration (U.S. FDA) for its Rufinamide Tablets USP, 200 mg and 400 mg, a therapeutic equivalent of Banzel® Tablets, 200 mg and 400 mg of Eisai, Inc. With respect to 180-day generic drug exclusivity, we note that Glenmark was one of the first ANDA applicants to submit a substantially complete ANDA for Rufinamide Tablets USP, 200 mg and 400 mg, with a paragraph IV certification. Therefore, with this approval, Glenmark is eligible for 180 days of shared generic drug exclusivity for Rufinamide Tablets USP, 200 mg and 400 mg.

According to IMS Health sales data for the 12 month period ending March 2016, the Banzel® market¹ achieved annual sales of approximately \$155.1 million.

Glenmark's current portfolio consists of 113 products authorized for distribution in the U.S. marketplace and 63 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, March 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 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.

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