

Press Release

For Immediate Release

Glenmark Pharmaceuticals receives ANDA approval for Teriflunomide Tablets, 7 mg and 14 mg

Mumbai, India, November 16, 2018: Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted final approval by the United States Food & Drug Administration (U.S. FDA) for Teriflunomide Tablets, 7 mg and 14 mg, a generic version of Aubagio^{®1} Tablets, 7 mg and 14 mg, of Sanofi-Aventis U.S., LLC.

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 Teriflunomide Tablets, 7 mg and 14 mg, with a paragraph IV certification. Therefore, with this approval, Glenmark is eligible for 180 days of shared generic drug exclusivity for Teriflunomide Tablets, 7 mg and 14 mg.

According to IQVIA[™] sales data for the 12 month period ending September 2018, the Aubagio[®] Tablets, 7 mg and 14 mg market² achieved annual sales of approximately \$1.6 billion*.

Glenmark's current portfolio consists of 142 products authorized for distribution in the U.S. marketplace and 57 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.

¹All brand names and trademarks are the property of their respective owners.

²Market includes brand and all available therapeutic equivalents

*IQVIA[™] National Sales Perspectives: Retail & Non-Retail, September 2018

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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.

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