

Press Release

For Immediate Release

Glenmark Pharmaceuticals receives tentative ANDA approval for Dimethyl Fumarate Delayed-Release Capsules, 120 mg and 240 mg

Mumbai, India; October 9, 2019: Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted tentative approval by the United States Food & Drug Administration (U.S. FDA) for Dimethyl Fumarate Delayed-Release Capsules, 120 mg and 240 mg, a generic version of Tecfidera^{®1} Capsules, 120 mg and 240 mg, of Biogen Inc.

According to IQVIA[™] sales data for the 12 month period ending August 2019, the Tecfidera[®] Capsules, 120 mg and 240 mg market² achieved annual sales of approximately \$3.7 billion*.

Glenmark's current portfolio consists of 161 products authorized for distribution in the U.S. marketplace and 49 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, August 2019

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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 80 Pharma & Biotech companies of the world in terms of revenue (SCRIP 100 Rankings published in the year 2019). 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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