

Press Release

For Immediate Release

Glenmark Pharmaceuticals Inc., USA receives tentative ANDA approval for Dronedarone Tablets, 400 mg

Mumbai, India, January 6, 2016: Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted tentative approval by the United States Food & Drug Administration (U.S. FDA) for its Dronedarone Tablets, 400 mg, the generic version of Multaq® Tablets, 400 mg of Sanofi-Aventis U.S., LLC. ‘Tentative approval’ means that FDA has concluded that a drug product has met all required quality, safety and efficacy standards, but is not eligible for marketing in the U.S. because of existing patent protections or exclusivities. Glenmark believes it is one of the first companies to have filed a substantially complete ANDA containing a Paragraph IV certification for Dronedarone Tablets and expects to be eligible for 180 days of generic drug exclusivity upon final FDA approval. Glenmark remains involved in a patent litigation in the U.S. District Court for the District of Delaware, wherein Sanofi and Sanofi-Aventis U.S., LLC has asserted its patents.

According to IMS Health sales data for the 12 month period ending November 2015, the Multaq® market achieved annual sales of approximately \$425.7 million.

Glenmark’s current portfolio consists of 104 products authorized for distribution in the U.S. marketplace and 62 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, November 2015

About Glenmark Pharmaceuticals Ltd:

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical company headquartered at Mumbai, India. It is ranked among the top 80 Pharma & Biotech companies of the world in terms of revenues. (SCRIP 100 Rankings published in the year 2014). 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 branded generics markets across emerging economies including India. GPL along with its subsidiary has 16 manufacturing facilities in five countries and has six R&D centers.

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