November 26, 2019

To,
Dy. General Manager
Department of Corporate Services,
BSE Ltd.,
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001.

To,
The Manager – Listing,
The National Stock Exchange of India Ltd.,
Plot No. C/1, G Block,
Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051.

Ref: Scrip Code: 532296

Dear Sir,

Sub: Glenmark Pharmaceuticals receives ANDA approval for Metformin Hydrochloride Extended-Release Tablets USP, 500 mg and 1000 mg

With reference to the subject mentioned above, kindly find attached media release which is self explanatory.

Request you to kindly take the same on record.

Thanking you,

Yours faithfully,

For Glenmark Pharmaceuticals Limited

HARISH

VINAYAK

KUBER

Digital signature

Harish Kuber
Company Secretary & Compliance Officer

Encl: as above
Glenmark Pharmaceuticals receives ANDA approval for Metformin Hydrochloride Extended-Release Tablets USP, 500 mg and 1000 mg

Mumbai, India; November 26, 2019: Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted final approval by the United States Food & Drug Administration (U.S. FDA) for Metformin Hydrochloride Extended-Release Tablets USP, 500 mg and 1000 mg, the generic version of Glumetza®1 Extended-Release Tablets, 500 mg and 1000 mg, of Salix Pharmaceuticals Inc.

According to IQVIA™ sales data for the 12-month period ending September 2019, the Glumetza® Tablets, 500 mg and 1000 mg market2 achieved annual sales of approximately $226.7 million*.

Glenmark’s current portfolio consists of 164 products authorized for distribution in the U.S. marketplace and 44 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 2019

-End-

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.

For further information, please contact:
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