

May 29, 2017

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

Ref: Scrip Name: GLENMARK

Dear Sirs,

**Sub:- Glenmark Pharmaceuticals receives ANDA approval for  
Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg and 20 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 Ltd.

  
Harish Kuber  
Company Secretary & Compliance Officer

**Glenmark Pharmaceuticals Ltd.**

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Registered office: B/2, Mahalaxmi Chambers, 22 Bhulabhai Desai Road, Mumbai 400 026

CIN No: L24299MH1977PLC019982 E: [complianceofficer@glenmarkpharma.com](mailto:complianceofficer@glenmarkpharma.com)

Press Release

For Immediate Release

## **Glenmark Pharmaceuticals receives ANDA approval for Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg**

**Mumbai, India; May 29, 2017:** Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted final approval by the United States Food & Drug Administration (U.S. FDA) for Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg, the generic version of Bystolic® Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg, of Forest Laboratories, LLC [Forest]. With respect to 180-day generic drug exclusivity, the FDA noted that Glenmark was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg. Therefore, with this approval, Glenmark may be eligible for 180 days of generic drug exclusivity for Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg.

Under the terms of the prior settlement agreement with Forest, Glenmark will be able to market and distribute its product under a license from Forest three months prior to the expiration of U.S. Patent No. 6,545,040, including any extensions and/or pediatric exclusivity, or earlier under certain circumstances.

According to IMS Health sales data for the 12 month period ending March 2017, the Bystolic® Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg market<sup>1</sup> achieved annual sales of approximately \$1.0 billion\*.

Glenmark's current portfolio consists of 116 products authorized for distribution in the U.S. marketplace and approximately 68 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.

<sup>1</sup>Market includes brand and all available therapeutic equivalents

\*IMS Health National Sales Perspectives: Retail & Non-Retail, March 2017

### **About Glenmark Pharmaceuticals**

Glenmark Pharmaceuticals Ltd. (GPL) is a global innovative pharmaceutical company with operations in more than 80 countries. Glenmark has a diverse pipeline with several compounds in various stages of clinical development primarily focused in the areas of oncology, respiratory disease, and dermatology. Glenmark's current respiratory pipeline is aimed at addressing the global public health burden of allergic rhinitis, asthma, and COPD, and includes four investigational treatments across the disease spectrum and devices. Headquartered in Mumbai, India, with U.S. headquarters in Mahwah, NJ, Glenmark has improved the lives of millions of patients by offering safe, affordable medications for nearly 40 years. For more information visit [www.glenmarkpharma.com](http://www.glenmarkpharma.com).

***For further information, please contact:***

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