

Press Release

For Immediate Release

**Glenmark Pharmaceuticals receives ANDA final approval for  
Tadalafil Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg;  
and receives ANDA tentative approvals for  
Gabapentin Enacarbil Extended-Release Tablets, 300 mg and 600 mg  
and Apremilast Tablets, 10 mg, 20 mg and 30 mg**

**Mumbai, India; December 31, 2020:** Glenmark Pharmaceuticals Limited (Glenmark), a research-led global pharmaceutical company has received final approval by the United States Food & Drug Administration (U.S. FDA) for Tadalafil Tablets USP, 2.5 mg, 5 mg, 10 mg and 20 mg, the generic version of Cialis<sup>®1</sup> Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg, of Eli Lilly and Company.

According to IQVIA<sup>™</sup> sales data for the 12 month period ending November 2020, the Cialis<sup>®</sup> Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg market<sup>2</sup> achieved annual sales of approximately \$125.5 million\*.

Glenmark has also received tentative approval by the U.S. FDA for Gabapentin Enacarbil Extended-Release Tablets, 300 mg and 600 mg, the generic version of Horizant<sup>®1</sup> Extended-Release Tablets, 300 mg and 600 mg, of Arbor Pharmaceuticals, LLC. The Horizant<sup>®</sup> market achieved annual sales of approximately \$99.5 million.

Additionally, Glenmark has received tentative approval for Apremilast Tablets, 10 mg, 20 mg and 30 mg, the generic version of Otezla<sup>®</sup> Tablets, 10 mg, 20 mg and 30 mg, of Amgen, Inc. The Otezla<sup>®</sup> Tablets, 10 mg, 20 mg and 30 mg market achieved annual sales of approximately \$2.7 billion.

Glenmark's current portfolio consists of 167 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.

### **About Glenmark Pharmaceuticals Ltd**

Glenmark Pharmaceuticals Ltd. (GPL) is a global research-led pharmaceutical company with presence across Generics, Specialty and OTC business with operations in over 50 countries. Glenmark's key therapy focus areas globally are respiratory, dermatology and oncology. 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). The company has been listed in the Dow Jones Sustainability Index (DJSI), under the category of emerging markets for the second consecutive year in a row. DJSI is one of the world's most respected and widely accepted sustainability benchmarks globally with only the top ranked companies in terms of Corporate Sustainability within each industry are featured in the index.

For more information, visit [www.glenmarkpharma.com](http://www.glenmarkpharma.com)

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<sup>1</sup>All brand names and trademarks are the property of their respective owners.

<sup>2</sup>Market includes brand and all available therapeutic equivalents

\*IQVIA™ National Sales Perspectives: Retail & Non-Retail, November 2020