

Press Release

For Immediate Release

**Glenmark Pharmaceuticals receives ANDA approval for
Theophylline Extended-Release Tablets, 300 mg and 450 mg:
Granted competitive generic therapy (CGT) designation and is eligible for
180 days of CGT exclusivity on the 450 mg**

Mumbai, India, June 4, 2021:– Glenmark Pharmaceuticals Limited (Glenmark) has received final approval by the United States Food & Drug Administration (U.S. FDA) for Theophylline Extended-Release Tablets, 300 mg and 450 mg, bioequivalent and therapeutically equivalent to the reference listed drug, Theophylline Extended-Release Tablets, 300 mg and 450 mg, of Alembic Pharmaceuticals Limited.

Glenmark has been granted a competitive generic therapy (CGT) designation for Theophylline Extended-Release Tablets USP, 450 mg, therefore, with this approval, Glenmark is the first approved applicant for such competitive generic therapy and is eligible for 180 days of CGT exclusivity upon commercial marketing of the 450 mg strength.

According to IQVIA™ sales data for the 12 month period ending April 2021, the Theophylline Extended-Release Tablets, 300 mg and 450 mg market² achieved annual sales of approximately \$47.8 million*.

Glenmark's current portfolio consists of 173 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.

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About Glenmark Pharmaceuticals

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 third 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

For further information, please contact:

Udaykumar Murthy

Senior Manager, Corporate Communications

Glenmark, Mumbai, India

Tel: +91 9960377617

Email: corpcomm@glenmarkpharma.com

References:

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, April 2021