

Press Release For Immediate Release

## Glenmark Pharmaceuticals receives ANDA approval for Diltiazem Hydrochloride Extended-Release Capsules USP, 60 mg, 90 mg, and 120 mg: Granted competitive generic therapy (CGT) designation and is eligible for 180 days of CGT exclusivity

Mumbai, India, March 23, 2021 – Glenmark Pharmaceuticals Limited (Glenmark) has received final approval by the United States Food & Drug Administration (U.S. FDA) for Diltiazem Hydrochloride Extended-Release Capsules USP, 60 mg, 90 mg, and 120 mg, the generic version of Cardizem<sup>®1</sup> SR Extended-Release Capsules, 60 mg, 90 mg, and 120 mg, of Biovail Laboratories Inc.

Glenmark has been granted a competitive generic therapy (CGT) designation for Diltiazem Hydrochloride Extended-Release Capsules USP, 60 mg, 90 mg, and 120 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.

According to IQVIA<sup>™</sup> sales data for the 12 month period ending January 2021, the Cardizem® SR Extended-Release Capsules, 60 mg, 90 mg, and 120 mg market<sup>2</sup> achieved annual sales of approximately \$56.7 million\*.

Glenmark's current portfolio consists of 170 products authorized for distribution in the U.S. marketplace and 42 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 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

## Glenmark Pharmaceuticals Ltd.



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

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

<sup>\*</sup>IQVIA™ National Sales Perspectives: Retail & Non-Retail, January 2021