

Press Release

For Immediate Release

Glenmark Pharmaceuticals receives ANDA approval for Bendamustine Hydrochloride for Injection, 25 mg/vial and 100 mg/vial

This is Glenmark's first injectable approval in the USA

Mumbai, March 28, 2016: Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted final approval by the United States Food & Drug Administration (U.S. FDA) for Bendamustine Hydrochloride for Injection, 25 mg/vial and 100 mg/vial, the therapeutic equivalent to the reference listed drug product, Treanda® for Injection, 25 mg/vial and 100 mg/vial, of Cephalon, Inc. Today marks Glenmark's first injectable granted approval by the U.S. FDA.

Under the terms of the prior settlement agreement, Glenmark will be able to launch its product on November 1, 2019, or earlier under certain circumstances. Glenmark was one of the first ANDA applicants to submit a substantially complete ANDA with a Paragraph IV certification, therefore, Glenmark may be eligible for 180 days of marketing exclusivity for Bendamustine Hydrochloride for Injection, 25 mg/vial and 100 mg/vial.

According to IMS Health sales data for the 12 month period ending January 2016, the Treanda® for Injection, 25 mg/vial and 100 mg/vial Market¹ achieved annual sales of approximately \$92.6 million*.

Glenmark's current portfolio consists of 110 products authorized for distribution in the U.S. marketplace and 59 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.

¹Market includes brand and all available therapeutic equivalents; lyophilized powder formulations only

*IMS Health National Sales Perspectives: Retail & Non-Retail, January 2016

About Glenmark Pharmaceuticals Ltd.:

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical organization headquartered at Mumbai, India. It is ranked among the top 80 Pharma & Biotech companies of the world in terms of revenue (*SCRIP 100 Rankings published in the year 2016*). 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 primarily focused in the areas of Inflammation [asthma/COPD, rheumatoid arthritis etc.] and Pain [neuropathic pain and inflammatory pain].

The company has a significant presence in the branded generics markets across emerging economies including India. GPL along with its subsidiary 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:

Rajdeep Barooah/Shibani Shah

Glenmark, Mumbai, India

Tel: [+91 22] 4018 9984/9348

Email: corpcomm@glenmarkpharma.com