glenmark
A new way for a new world

December 14, 2017

To,
Dy. General Manager
Department of Corporate Services,
BSE Ltd.,
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001.

Ref: Scrip Code: 532296

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 Name: GLENMARK

Dear Sirs,

Sub: Glenmark Pharmaceuticals Announces Top-Line Results from a Phase 3 Safety Study Evaluating Ryaltris™ in Patients with Perennial Allergic Rhinitis

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 Limited

Harish Kuber
Company Secretary & Compliance Officer

Encl: as above

Glenmark Pharmaceuticals Ltd.
Glenmark House, B D Sawant Marg, Andheri (E), Mumbai - 400 099, India
T: 91 22 4018 9999 F: 91 22 4018 9988 CIN No: L24299MH1977PLC019982 W: www.glenmarkpharma.com
Registered office: B/2, Mahalaxmi Chambers, 22 Bhulabhai Desai Road, Mumbai 400 026 E: complianceofficer@glenmarkpharma.com

Press Release – For Immediate Release

Glenmark Pharmaceuticals Announces Top-Line Results from a Phase 3 Safety Study Evaluating Ryaltris™ in Patients with Perennial Allergic Rhinitis

Ryaltris (mometasone furoate (25 mcg) and olopatadine hydrochloride (665 mcg)), formerly GSP 301 Nasal Spray, has been conditionally accepted by the FDA as the brand name

Glenmark remains on course to file the company's first New Drug Application in the first quarter of CY 2018

Mumbai, India; December 14, 2017 – Glenmark Pharmaceuticals, a global pharmaceutical company, today announced that it met its primary clinical endpoint in a Phase 3 study evaluating the safety of Ryaltris™ (RY • al • tris), an investigational fixed-dose combination nasal spray, in perennial allergic rhinitis (PAR). Ryaltris has been conditionally accepted as the brand name for GSP 301 Nasal Spray by the U.S. Food & Drug Administration (FDA). Glenmark plans to submit the company's first new drug application (NDA) to the FDA for Ryaltris for the treatment of patients with seasonal allergic rhinitis (SAR) in the first quarter of CY 2018.

> *"Ryaltris has been extensively studied in three Phase 3 trials for SAR, and we are pleased that the addition of this long-term study in patients suffering with PAR met the primary safety and secondary efficacy endpoints. Collectively, these data suggest that Ryaltris is effective and well-tolerated," said Fred Grossman, President and Chief Medical Officer at Glenmark Pharmaceuticals. "We have worked closely with the FDA on the clinical development program for Ryaltris, and look forward to providing robust data to support its potential approval."*

This Phase 3, U.S.-based trial was a three-arm, double-blind, randomized, parallel group, placebo-controlled safety study that enrolled 601 adults and adolescents 12 years of age and older with at least a two-year history of PAR. Patients were randomized to 52 weeks of twice-daily treatment with Ryaltris, or two different formulations of a placebo nasal spray. All trial arms used the same nasal spray delivery system. The study also assessed efficacy, as change from baseline in average morning patient-reported reflective Total Nasal Symptom Score (rTNSS), as a secondary endpoint.

For the primary endpoint, all treatments administered in the trial were well-tolerated, and the majority of treatment emergent adverse events (TEAEs) were mild-to-moderate in severity. The most frequent TEAEs reported with Ryaltris included nosebleeds (4.6%), headache (4.1%) and a decrease in taste sensitivity (2.0%). In addition, on the secondary efficacy endpoint, treatment with Ryaltris demonstrated statistically significant and clinically meaningful improvement from baseline in average morning patient-reported rTNSS, compared to placebo ($p<0.0001$) over 52 weeks of treatment.

> *"Glenmark has rapidly evolved from a company with a thriving generic pharmaceutical business to one that is also discovering new treatments, and researching devices that deliver these treatments in new ways," said Robert Matsuk, President, North America & Global API at Glenmark Pharmaceuticals. "Ryaltris is an important first step in this evolution, and the realization of the potential in Glenmark's pipeline has only just begun. Over the next 10 years, Glenmark believes that the investments made in the Company's robust pipeline will continue to produce a variety of new and innovative treatment options."*

Data from this trial have not yet been published. Glenmark will be submitting these data for presentation at upcoming scientific meetings and publication in a peer-reviewed journal.

About Glenmark's Respiratory Pipeline

Glenmark's respiratory pipeline is specifically aimed at addressing the global public health burden of allergic rhinitis, asthma, and chronic obstructive pulmonary disease (COPD), and includes five investigational treatments across the disease spectrum and devices. This includes Ryaltris (GSP 301 Nasal Spray), a combination steroid plus antihistamine nasal spray for the treatment of allergic rhinitis, which has completed three Phase 3 trials and is preparing for an NDA submission. It also includes GSP 304, currently in Phase 2 trials, which is a long-acting muscarinic receptor agonist being investigated as a nebulized treatment for COPD; GBR 310 (omalizumab), a proposed biosimilar candidate intended for the treatment of allergic asthma and chronic idiopathic urticaria; and GRC 39815, which is pre-clinically being investigated for the treatment of COPD.

About Glenmark Pharmaceuticals

Glenmark Pharmaceuticals Ltd. (GPL) is a global innovative pharmaceutical company with operations in more than 50 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 has improved the lives of millions of patients by offering safe, affordable medications for nearly 40 years. For more information, visit **glenmarkpharma.com**

For further information, please contact:
Ramkumar Uppara and Shibani Shah
+91 22 401 89984/348
corpcomm@glenmarkpharma.com