

Press Release

For Immediate Release

## **Glenmark Pharmaceuticals Receives FDA Clearance of IND for GSP 304**

*Company to Initiate Phase 2 Clinical Study in Patients with Chronic Obstructive Pulmonary  
Disease*

**MUMBAI, March 8, 2017** – Glenmark Pharmaceuticals, a global pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) cleared the Company's Investigational New Drug (IND) application to begin a Phase 2 study of GSP 304 (tiotropium bromide) for administration by nebulization for the long term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD).

Glenmark plans to initiate clinical development with a Phase 2 study of GSP 304, a new orally administered formulation, in subjects with mild to moderate COPD, as determined by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria. The efficacy, pharmacokinetics, and safety profiles of currently available formulations of tiotropium bromide are well established.

“Respiratory is a core area of focus for Glenmark as we continue to harness our heritage in generics and evolve into a specialty, innovation-focused company,” said Fred Grossman D.O., President and Chief Medical Officer at Glenmark Pharmaceuticals Inc. “Moving GSP 304 into Phase 2 is a great example of that focus and, if approved, will be the first nebulized form of tiotropium bromide. This milestone further affirms our goal of providing new treatment options that meet significant unmet medical needs.”

### **About the Clinical Study**

The Phase 2, U.S.-based study is a 5-arm, parallel group, randomized, placebo-controlled, double-blind, dose-ranging study with an active open-label comparator (SPIRIVA® RESPIMAT®). Approximately 155 subjects will be randomized and treated for 3 weeks in order to inform the dose selection for Phase 3 using pharmacokinetic and pharmacodynamic parameters.

### **About Glenmark Pharmaceuticals**

Glenmark Pharmaceuticals Ltd. (GPL) is a global innovative pharmaceutical company with operations in more than 80 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's current respiratory pipeline is aimed at addressing the global public health burden of allergic rhinitis, asthma, and COPD, and includes four investigational treatments across the disease spectrum and devices. Headquartered in Mumbai, India, with U.S. headquarters in Mahwah, NJ. Glenmark has improved the lives of millions of patients by offering safe, affordable medications for nearly 40 years. For more information visit [www.glenmarkpharma.com](http://www.glenmarkpharma.com).

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