Press Release **For Immediate Release**

Glenmark Pharmaceuticals Initiates Clinical Investigation for GBR 310, its Proposed Biosimilar Candidate for XOLAIR®

Mumbai, India; April 25, 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 initiate a first-in-human study of GBR 310, a proposed biosimilar, which will assess its pharmacokinetics in comparison to XOLAIR® (omalizumab) in healthy adult volunteers between 18 – 65 years of age.

"This marks the second IND activation in 2017 for our growing respiratory portfolio," said Kurt Stoeckli, President and Chief Scientific Officer at Glenmark Pharmaceuticals. "In the seven years since the U.S. approval process for biosimilar medicines was signed into law, there have been few candidates successfully developed. GBR 310 has the potential to be among the first biosimilar candidates to be submitted for approval for a respiratory or allergic disease."

GBR 310 is a recombinant DNA-derived humanized immunoglobulin G1 kappa monoclonal antibody. Its current proposed indication is for the treatment of allergic asthma and chronic idiopathic urticaria. The reference product for GBR 310 is omalizumab, available under the brand name XOLAIR.

According to IMS sales data for the 12-month period ending February 2017, annual sales of XOLAIR 150 mg injection was approximately $1.7 Billion in the U.S.[1]

About Allergic Asthma and Chronic Idiopathic Urticaria

Asthma is one of the most common diseases in children and affects more than 18 million people older than 18 in the U.S.[2,3] Allergic asthma is unique because it is triggered by exposure to year-round allergens like pet dander and dust mites. Allergies trigger asthma attacks in 60-90 percent of children with asthma and in approximately 50 percent of adults.[4]

Urticaria is a common skin disease that presents as spontaneously recurring hives or welts. It occurs across all age groups and about one percent of the population suffers from a chronic form of the disease.[5] Among this group, 70% of people report symptoms that last for more than one year and 14% report symptoms that last for more than five years.[6]

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 four investigational treatments across the disease spectrum and devices. This includes GSP 301, currently in Phase 3 trials, which is a combination steroid plus antihistamine nasal spray being investigated for the treatment of allergic rhinitis; GSP 304, currently in Phase 2 trials, which is a long acting muscarinic receptor agonist being investigated as a nebulized treatment for COPD; 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 www.glenmarkpharma.com/usa.

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References:

1. QuintilesIMS. National Sales Perspectives™. March 2016 to February 2017.
2. U.S. Centers for Disease Control and Prevention. What Is Asthma? http://www.cdc.gov/asthma/faqs.htm.
3. U.S. Centers for Disease Control and Prevention. National Current Asthma Prevalence. http://www.cdc.gov/asthma/most_recent_data.htm.
4. Kelly W, et al. Allergic and Environmental Asthma Overview of Asthma. http://emedicine.medscape.com/article/137501-overview.
5. Powell RJ, Du Toit GL, Siddique N, et al. BSACI guidelines for the management of chronic urticaria and angio-oedema. *Clin Exp Allergy.* 2007 May;37(5): 631–50.
6. Toubi E, Kessel A, Avshovich N, et al. Clinical and laboratory parameters in predicting chronic urticaria duration: a prospective study of 139 patients. *Allergy.* 2004 Aug;59(8):869–73.