Press Release – For Immediate Release

Glenmark Pharmaceuticals Announces Encouraging Phase 1 Results Supporting Biosimilarity Criteria for GBR 310 Compared to the Reference Product Omalizumab

Glenmark is seeking use of GBR 310 for the same indications as the reference biologic for the treatment of allergic asthma and chronic idiopathic urticaria (CIU)

Mumbai, India; July 26, 2018 – Glenmark Pharmaceuticals, a global pharmaceutical company, today announced results from a Phase 1 study that suggest similarity in pharmacokinetic, pharmacodynamic, safety and immunogenicity profiles between Glenmark's GBR 310 proposed biosimilar and reference product omalizumab, marketed in the U.S. under the brand name Xolair®.[1]

> *"We are pleased with the rapid progress made in the development of GBR 310, and look forward to meeting with the FDA this fall with the goal of advancing this proposed biosimilar candidate," said Kurt Stoeckli, President and Chief Scientific Officer at Glenmark Pharmaceuticals. "This progress is owed to the growth of talent at our global R&D centers, who continue to expand and take on new capabilities and challenges."*

GBR 310 is a recombinant DNA-derived humanized immunoglobulin G_1 kappa monoclonal antibody. The proposed indications for GBR 310 are for the treatment of allergic asthma and chronic idiopathic urticaria (CIU). The now completed Phase 1 study enrolled 168 healthy adult volunteers, randomized 1:1 to receive either a single 150 mg dose of GBR 310 subcutaneously (SC) or a single 150 mg dose of U.S.-sourced omalizumab SC. The total duration of participation for each volunteer was approximately 127 days, including screening, in-house stay, outpatient and follow-up visits.

According to IQVIA sales data for the 12-month period ending May 2018, annual sales of Xolair were approximately $2.0 billion in the U.S.[2]

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.[3,4] 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 and in approximately 50 percent of adults with asthma.[5]

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.[6] Among this group, 70 percent of people report symptoms that last for more than one year and 14 percent report symptoms that last for more than five years.[7]

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 investigational treatments across the disease spectrum. This includes Ryaltris (olopatadine hydrochloride [665 mcg] and mometasone furoate [25 mcg], formerly GSP 301 nasal spray), an investigational combination antihistamine plus steroid nasal spray for the treatment of seasonal allergic rhinitis. It also includes GBR 310 (omalizumab), a proposed biosimilar candidate intended for the treatment of allergic asthma and chronic idiopathic urticaria; and GRC 39815, which is being investigated pre-clinically for the treatment of COPD and other respiratory diseases.

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 **https://www.glenmarkpharma-us.com/**.

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References:

1. Xolair is a registered trademark of Genentech USA, Inc. and Novartis Pharmaceuticals Corporation indicated for the treatment of moderate to severe persistent asthma in patients six years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled via inhaled corticosteroids; and for the treatment of chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.
2. IQVIA. National Sales Perspectives™. May 2018.
3. U.S. Centers for Disease Control and Prevention. What Is Asthma? http://www.cdc.gov/asthma/faqs.htm.
4. U.S. Centers for Disease Control and Prevention. National Current Asthma Prevalence. http://www.cdc.gov/asthma/most_recent_data.htm.
5. Kelly W, et al. Allergic and Environmental Asthma Overview of Asthma. http://emedicine.medscape.com/article/137501-overview.
6. 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.
7. 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.