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Glenmark Pharma announces positive Results of GBR 310

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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)

Glenmark Pharmaceuticals, a global pharmaceutical company 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®.

GBR 310 is a recombinant DNA-derived humanized immunoglobulin G1 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.