BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Glenmark initiates clinical investigation for respiratory drug

28 April 2017 | News

This marks the second IND activation in 2017 for the growing respiratory portfolio of Glenmark.

Global pharmaceutical major Glenmark Pharmaceuticals has received the US Food and Drug Administration (USFDA) approval for the company's Investigational New Drug (IND) application to initiate a first-in-human study of GBR 310, a proposed biosimilar candidate for Xolair which is used to treat persistent asthma in patients 6 years of age or older.

This marks the second IND activation in 2017 for the growing respiratory portfolio of Glenmark.

GBR 310 is a recombinant DNA-derived humanised 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 Intercontinental Marketing Statistics sales data for the 12-month period ending February 2017, annual sales of Xolair 150 mg injection was approximately $1.7 billion in the US.