

Press Release

For Immediate Dissemination

Glenmark's novel monoclonal antibody GBR 830 to enter Phase 2 clinical studies in Atopic Dermatitis and Celiac Disease in US and Europe

- GBR 830 completes clinical Phase 1 successfully in The Netherlands
- The antibody has been well tolerated with a favourable pharmacokinetic profile
- GBR 830 is the first OX40 antagonist to complete Phase 1 clinical studies

Mumbai, India, September 03, 2015: Glenmark Pharmaceuticals S.A., a wholly owned Swiss subsidiary of Glenmark Pharmaceuticals Ltd., announced today that GBR 830, a novel monoclonal antibody has completed clinical phase 1 dosing. GBR 830 is an antagonist of OX40, a costimulatory receptor expressed on T cells mediating T cell activation and survival.

Glenmark has now completed clinical Phase I studies for GBR 830 in the Netherlands. GBR 830 was well tolerated and its safety & pharmacokinetics profile in healthy volunteers fully support the transition into clinical Phase 2 studies. Preparations for initiating Phase 2 studies in both atopic dermatitis and celiac disease in the US and Europe are well advanced. Glenmark expects dosing to commence in the next few months. These are indications with an unmet medical need and in addition also offer the possibility to characterize the mode of action of GBR 830 in detail in these patient populations.

GBR 830 targets activated T cells. This cell type drives the pathology in most autoimmune diseases including rheumatoid arthritis, multiple sclerosis and inflammatory bowel disease.

Commenting on the progress with GBR 830, **Glenn Saldanha, Chairman & Managing Director, Glenmark Pharmaceuticals** said, "We are excited about the progress of GBR 830, the first OX40 Antagonist globally to successfully complete Phase 1 studies. OX40 is a very well validated target with the potential to treat a wide array of autoimmune diseases. However, discovering antibodies that inhibit OX40 and do not have agonistic properties which would lead to unwanted side effects has been challenging for the industry. Based on our data GBR 830 is the best in class OX40 antagonistic antibody.

The progress of this novel monoclonal antibody into Phase 2 for atopic dermatitis and celiac disease indications in the US and Europe reaffirms Glenmark's capabilities in the area of novel monoclonal antibodies and also the cutting edge work done at our Biologics Research Centre in Switzerland. There is a significant unmet medical need for both indications and we will expeditiously develop this molecule for patients."

Atopic Dermatitis

Atopic dermatitis (AD) is a chronic, immune-mediated, inflammation of the skin with involvement of activated T cells. Chronic and/or relapsing lesions, associated with itching and scratching are the hallmarks of the disease. The prevalence of AD is estimated to be between 1% and 3% of adults and up to 20% in children. For many patients, topical therapies are not effective for keeping the disease under control and in Europe the only approved systemic therapies to treat AD are prednisone and cyclosporine. Moderate-to-severe atopic dermatitis can negatively impact patients' lives and is associated with a high burden to society both in terms of direct costs of medical care and prescription drugs, as well as loss of productivity. No monoclonal antibodies are currently approved for the treatment of AD.

Celiac Disease

Celiac disease is an autoimmune disease which is triggered by consumption the gluten protein, which is found in wheat, barley and rye. Symptoms include pain and discomfort in the digestive tract, chronic constipation and diarrhoea, anaemia and fatigue. Globally, coeliac diseases affects between 1-2% of the population. There is no medical treatment available besides maintaining a strictly gluten-free diet. Maintaining a life-long gluten-free diet is difficult as well as expensive to maintain and may affect quality of life including loss of productivity due to social restrictions and inadvertent gluten ingestion. Modulation of the autoimmune response in celiac disease patients with the goal of a relaxation of the strict dietary requirements is seen as a possible therapeutic approach to improve their quality of life.

Glenmark's Novel Biologics Entity pipeline

Glenmark currently has four monoclonal antibodies in the Novel Biologics Entity (NBE) pipeline with three of them in active clinical development programs. First, GBR 500 (SAR339658, vatelizumab), a monoclonal antibody represents a first-in-class opportunity indicated for the treatment of Multiple Sclerosis (MS) and other autoimmune diseases. GBR 500 has been licensed to Sanofi and is in Phase II trials in the US. The second monoclonal antibody, GBR 900 targets the TrkA receptor for chronic pain and is currently in clinical Phase I. This project is developed under license from Lay Line Genomics S.p.A., an Italian based Company. Monoclonal antibodies specific for TrkA represent a first-in-class opportunity for the treatment of chronic pain, which has a high level of unmet medical need. GBR 830, a best in class OX40 antagonist for autoimmune diseases recently completed Phase I clinical development. GBR 1302, a HER2xCD3 bispecific antibody, is the first clinical candidate based on Glenmark's proprietary best in class BEAT® platform and also GBR 1302 is Glenmark's first clinical candidate targeting oncology indications. The BEAT® antibody technology platform facilitates the efficient development and manufacturing of antibodies with dual specificities called bispecific antibodies.

About Glenmark Pharmaceuticals Ltd

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical company and ranked among the top 80 Pharma & Biotech companies of the world in terms of revenues. Glenmark is a leading player in the discovery of new molecules both NCEs and NBEs. Glenmark has several molecules in various stages of clinical development and primarily focused in the areas of Inflammation, Pain and Oncology. The company has significant presence in branded formulations across emerging economies including India. Glenmark also has significant presence in the generics market of the US and Europe.

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