**Press Release** **For Immediate Dissemination**

# Glenmark announces the Discovery and Initiation of IND enabling studies of a novel biologics entity, GBR 401, targeting Lymphomas and Leukemia's of B-cell origin

- Glenmark's first novel molecule for an oncology indication
- GBR 401 is a monoclonal antibody targeting CD19. The antibody is implicated in treatment of B cell malignancies and inflammatory disorders mediated by B lymphocytes
- CD19 is expressed earlier and more broadly in B-cell development than CD20 and represents a promising treatment approach
- GBR401 has been developed using an advanced technology platform that greatly enhances the efficacy of the antibody and has been developed completely in-house by Glenmark
- Glenmark will file for Phase I trials in Q4 FY 2011-12

**March 31, 2011 –** Glenmark Pharmaceuticals S.A. (GPSA), a wholly owned subsidiary of Glenmark Pharmaceuticals Limited India (GPL), announces the discovery and initiation of IND enabling studies of a Novel Biological Entity (NBE) lead candidate, GBR 401, an anti-CD19 monoclonal antibody. GBR 401 is developed completely in-house by Glenmark's Biologics Research Centre located in Switzerland.

The disease areas primarily targeted by GBR 401 are lymphomas and leukemia's of B-cell origin. Lymphomas are cancers originating from the lymphatic system. Non-Hodgkin's lymphoma (NHL), a type of B cell lymphoma, is the most common form of blood cancer. Leukemia is a cancer of the white blood cells. Within the seven major markets comprising of US, Europe Top 5 markets and Japan, new cases of NHL and leukemia's of B cell origin were estimated at 126,000 and 34,000 respectively. In addition the CD19 target holds potential for treatment of inflammatory disorders such as rheumatoid arthritis.

GBR 401 shows great promise to emerge as a valuable therapeutic option to treat patients affected with B-cell malignancies. GBR 401 has demonstrated strong anti-tumour potency and anti-proliferative apoptotic activity in several *in*-vitro and *in*-vivo studies. CD19 is known to be expressed earlier and more broadly in B-cell development than CD20, the latter being the target of the worlds second largest selling anti-cancer biotech product rituximab (Rituxan® / MabThera®) whose annual 2010 sales were in excess of US$6 billion. Glenmark will pursue further development of GBR 401 to accelerate its entry into clinical trials.

**Commenting on this milestone, Mr. Glenn Saldanha, CEO & MD, Glenmark Pharmaceuticals mentioned** "We are excited to announce GBR 401, which has been developed completely in-house leveraging our biologics antibody know-how. We are confident that the antibody expertise and product development capabilities of the Switzerland Biologics Research Centre will continue to enrich the Glenmark discovery pipeline."

"Targeting CD19 is a promising approach to treat B-cell malignancies. Further, GBR 401 has been developed using a technologically advanced platform that greatly enhances the efficacy of the antibody" **said Dr. Michael Buschle, President-Biologics, Glenmark Pharmaceuticals S.A., Switzerland.**

## About CD19 Target

Antibody inhibitors or cytotoxic antibodies against CD19 have the potential to treat a plethora of B cell or antibody-mediated diseases including malignancies and autoimmune diseases. CD19 forms part of the B cell co-receptor in conjunction with CD81 and CD21. It has no known ligand and is a critical signal transduction molecule that regulates B lymphocyte development, activation, and differentiation. It is present on B cells from the earliest recognizable B-lineage cells during development within the bone marrow to B-cell blasts but is lost on maturation to plasma cells. CD19 is used as the primary marker for the identification of B cell malignancies so its use as a target is understandable and as the B cell is also the producer of autoimmune antibodies in diseases such as systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA) then the removal of these cells will also benefit sufferers.

## Glenmark's Novel Biologics Entity pipeline

With the addition of GBR 401 to the pipeline, Glenmark will now have four monoclonal antibodies in the Novel Biologics Entity (NBE) pipeline. First, GBR 500, a monoclonal antibody represents a first-in-class opportunity indicated for the treatment of Inflammatory Bowel Disease (IBD) and Multiple Sclerosis (MS). GBR 500 has completed Phase I trials in the US and is the first novel monoclonal antibody developed by an Indian Company in the US. The second monoclonal antibody product, GBR 600, is a highly specific platelet inhibitor for the prevention of von Willebrand Factor (vWF) mediated diseases. GBR 600 has received approval for initiation of Phase I trials in Europe. Further, in Sept 2010 Glenmark received the exclusive license to the monoclonal antibody BXL1H5 i.e. GBR 900 including the exclusive target license to commercialize monoclonal antibodies against TrkA receptor for pain from Lay Line Genomics, an Italian based Company. TrkA is a promising target and monoclonal antibodies specific for TrkA represent a first- in-class opportunity for the treatment of chronic pain, which has a high level of unmet need. GBR 900 is in the pre-clinical stage of development and will be developed further by Glenmark Swiss R&D center

## About Glenmark

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical company. It is a leading player in the discovery of new molecules both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has eight molecules in various stages of clinical development and is primarily focused in the areas of Inflammation [asthma/COPD, rheumatoid arthritis etc.] and Pain [neuropathic pain and inflammatory pain]. The company has a significant presence in branded generics markets across emerging economies including India. It sells its products in over 70 countries worldwide. Through its subsidiary, Glenmark Generics Limited it has a significant present in the US and is among the leading generics organization in the country. GPL along with its subsidiary has twelve manufacturing facilities in four countries and has five R&D centres.

####

***For further information, please contact:***
Jason D'Souza
Glenmark, Mumbai, India; Tel: [+91-22-] 40189919 / 40189993
e-mail : media@glenmarkpharma.com