

Press Release

For Immediate Dissemination

Glenmark enters Oncology with the Discovery and the Initiation of IND enabling Studies of an innovative bispecific Antibody

- **GBR 1302 is the first bispecific antibody based on Glenmark's proprietary BEAT platform**
- **GBR 1302 is Glenmark's first clinical candidate targeting oncology indications**

August 20, 2014 – 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 clinical development candidate, GBR 1302, a HER2xCD3 bispecific antibody. GBR 1302 was discovered and developed by the Glenmark Biologics Research Centre located in La Chaux-de-Fonds, Switzerland. GBR 1302 is based on Glenmark's innovative BEAT antibody technology platform which facilitates the efficient development and manufacture of antibodies with dual specificities, so-called bispecific antibodies. GBR 1302 is the first clinical development candidate based on the BEAT technology. Glenmark expects to obtain approval for the initiation of clinical studies during this financial year.

HER2, also known as HER2/neu, or receptor tyrosine-protein kinase erbB-2, is the target of the antibody cancer drugs trastuzumab, pertuzumab and trastuzumab emtansine and is involved in breast cancer and ovarian cancer.

GBR 1302's mode of action is different from current HER2 targeting antibodies. It redirects cytotoxic T cells through its CD3 binding arm onto HER2 expressing cancer cells and induces the killing of the cancer cells. The killing of cancer cells by GBR 1302 is more rapid, more complete and not subject to the same resistance escape mechanisms as competing therapies.

BEAT (Bispecific Engagement by Antibodies based on the T cell receptor) is a proprietary best in class platform of Glenmark. Engaging two targets with one bispecific antibody is an attractive concept to design new therapeutics. For the past 20 years, bispecific antibodies have been a challenge to the industry since all bispecific formats developed so far have had stability and/or manufacturing issues. With the invention of the BEAT technology Glenmark's scientists have now overcome these bottlenecks and GBR 1302 is the first drug candidate based on this antibody engineering breakthrough technology.

Commenting on this milestone, Dr. Michael Buschle, Chief Scientific Officer & President - Biologics, Glenmark Pharmaceuticals mentioned "GBR 1302 is significant for Glenmark on multiple levels: It is our first bispecific antibody, it is our first antibody based on our proprietary BEAT antibody engineering platform and it represents the entry of Glenmark into the Oncology innovator space, which has a huge commercial potential."

Glenmark's Novel Biologics Entity pipeline

With the addition of GBR 1302 to the pipeline, Glenmark has now four monoclonal antibodies in the Novel Biologics Entity (NBE) pipeline with three of them undergoing active clinical development. First, GBR 500, 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 need. The third antibody is GBR 830, a best in class OX40 antagonist for autoimmune diseases which recently entered Phase I clinical development.

About Glenmark

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical company headquartered at Mumbai, India. It is ranked among the top 80 Pharma & Biotech companies of the world in terms of revenues. (SCRIP 100 Rankings published in the year 2014). Glenmark is a leading player in the discovery of new molecules both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has several 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. GPL along with its subsidiary has 14 manufacturing facilities in four countries and has six R&D centers. Its subsidiary, Glenmark Generics Limited services the requirements of the US and Western Europe generics markets. The API business sells its products in over 80 countries, including the US, various countries in the EU, South America and India.

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