

Press Release

For Immediate Dissemination

Glenmark announces the Discovery and Initiation of IND-enabling studies of a novel Bispecific Monoclonal Antibody targeting EGFR

- Glenmark is advancing its oncology portfolio with the addition of GBR 1372, a bispecific monoclonal antibody from Glenmark's BEAT® technology platform targeting EGFR through redirected killing by T cells
- GBR 1372 has the potential to target EGFR expressing cancer cells independent of RAS-family mutations which drive resistance to current EGFR targeting drugs
- GBR 1372 is the third Bispecific Antibody and also Glenmark's third clinical candidate targeting an oncology indication

Mumbai; September 6, 2016: Glenmark Pharmaceuticals S.A. (GPSA), a wholly owned subsidiary of Glenmark Pharmaceuticals Limited India (GPL), has announced the discovery and initiation of IND-enabling studies for a novel clinical development candidate, GBR 1372. GBR 1372 adds to Glenmark's expanding oncology portfolio of biologics including GBR 1302 (HER2xCD3 bispecific antibody) and GBR 1342 (CD38xCD3 bispecific antibody) based on its proprietary BEAT® technology.

The epidermal growth factor receptor EGFR is a member of the ErbB family of receptor tyrosine kinases. EGFR is a well-established target for lung cancer and colorectal cancer. Current drugs prevent signaling through EGFR by blocking ligand binding or inhibiting its protein kinase activity but they cause considerable side effects and are not active against cancers with Ras mutations. Mutations in Ras genes continuously switch on intracellular signaling networks and make the tumors independent of stimulation by growth factor receptors such as EGFR and drugs that target EGFR are not currently indicated for patients with Ras mutations.

GBR 1372 kills cancer cells through redirecting T cells via its anti CD3-binding arm to EGFR expressing cancer cells through its EGFR-binding arm. Glenmark scientists in Switzerland have demonstrated preclinically that GBR 1372 is indeed equally active against EGFR expressing cancer cell lines – independent of their RAS mutation status.

Glenmark is likely to file an IND with the U.S. FDA in the second half of the next financial year FY 2018.

Commenting on this development, Mr. Glenn Saldanha, Chairman & MD, Glenmark Pharmaceuticals said, "We remain excited about the progress of our novel biologics pipeline. With the addition of GBR 1372, the quality of our biologics pipeline continues to improve. We continue to make strides as we transition to a global innovation led pharmaceutical organization".

Dr. Fred Grossman, Chief Medical Officer, Glenmark Pharmaceuticals mentioned, "We look forward to advancing GBR 1372 into clinical development in the near future".

BEAT® (Bispecific Engagement by Antibodies based on the T cell receptor) is Glenmark's technology for production of bispecific antibodies. Engaging two targets with one bispecific antibody is a novel concept to design new therapeutics. For the past 20 years, bispecific antibodies have been a challenge to the industry since most bispecific formats developed thus far have stability and/or manufacturing issues. With the invention of the BEAT® technology Glenmark's scientists have now overcome these hurdles and are able to efficiently engineer and manufacture bispecific antibodies.

NBE research pipeline:

Glenmark presently has a pipeline of six Novel Biologics Entity (NBE) in various stages of pre-clinical and clinical development. Glenmark's novel molecule 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, Italy. 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 830, a best in class OX40 antagonist for autoimmune diseases is currently in Phase II clinical development for atopic dermatitis. The development of OX40 antagonists has been very challenging and Glenmark has achieved a significant milestone with the successful generation of an antagonistic OX40 monoclonal antibody coupled with generation of data validating the role of OX40 in autoimmune diseases.

GBR 1302 is the first clinical candidate based on Glenmark's proprietary best in class BEAT® platform. GBR 1302 is also 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. GBR 1302, antibody has successfully completed the preclinical evaluation phase. In pre-clinics, GBR 1302 has demonstrated superiority over current antibody therapies against most HER2 positive cancers, including breast cancer. GBR 1342, a CD38xCD3 bispecific antibody is the second clinical development candidate based on the BEAT® technology. GBR 1342 targets CD38, a target for multiple myeloma and potentially other malignancies of hematopoietic origin. Glenmark has initiated IND-enabling studies for GBR 1342 and is committed to moving GBR 1342 rapidly into clinical trials.

About Glenmark:

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical organization headquartered at Mumbai, India. It is ranked among the top 80 Pharma & Biotech companies of the world in terms of revenue (SCRIP 100 Rankings published in the year 2016). 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 the branded generics markets across emerging economies including India. GPL along with its subsidiary has 16 manufacturing facilities across four countries and has five R&D centers. The Generics business of Glenmark services the requirements of the US and Western European 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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