Press Release **For Immediate Dissemination**

Glenmark's Bi-Specific Antibody - GBR 1302 to enter Phase I trials

- GBR 1302, a HER2xCD3 bi-specific antibody has successfully completed the preclinical evaluation phase
- **Preclinically, GBR 1302 has demonstrated superiority over current antibody therapies against most HER2 positive cancers, including breast cancer**
- The phase 1 trial application for this antibody has been submitted to German regulatory authorities.
- GBR 1302 has the potential to be used in the treatment a broad array of cancers including breast cancer
- If confirmed in clinical trials, GBR 1302 could constitute an innovative treatment for HER2 positive cancers, potentially superior to the currently available monoclonal antibody treatments

Mumbai, India September 15, 2015: Glenmark Pharmaceuticals S.A. (GPSA), a wholly owned subsidiary of Glenmark Pharmaceuticals Limited India (GPL), announces the completion of Phase 1 supporting studies and the submission of a clinical trial application to the Paul-Ehrlich Institute in Germany with a novel clinical development candidate, GBR 1302. GBR 1302 is a HER2xCD3 bi-specific antibody based on Glenmark's proprietary BEAT™ platform. GBR 1302 is the first clinical development candidate based on the BEAT™ technology. Glenmark expects to obtain approval for the initiation of clinical studies with GBR1302 during this financial year.

GBR 1302 material for Phase 1 clinical trials was manufactured in Glenmark GMP production unit in Switzerland. HER2, also known as HER2/neu, or receptor tyrosine-protein kinase erbB-2, is the target of the multibillion dollar antibody cancer drugs trastuzumab, pertuzumab and trastuzumab emtansine and is implicated in breast cancer, ovarian, gastric, and certain uterine cancers.

Commenting on this milestone, Dr. Michael Buschle, Chief Scientific Officer & President - Biologics, Glenmark Pharmaceuticals said "We have high expectations for GBR 1302. During the preclinical characterization of the bi-specific antibody we have discovered that GBR 1302 does not only kill trastuzumab resistant cancer cells, but also very efficiently kills cancer cells with a weak expression of HER2 against which all current HER2 targeting antibodies are not effective"

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. Preclinically, the killing of cancer cells by GBR 1302 is more rapid, more complete and not expected to be subject to the same resistance escape mechanisms as therapies directed against HER2.

Preclinically, GBR 1302 has demonstrated superiority over current antibody therapies for breast cancer in two important areas:

- GBR 1302 is able to kill cancer cells which are resistant to killing by Herceptin (trastuzumab).
- GBR 1302 is able to kill cancer cells with an intermediate expression level of HER2 against which Herceptin (trastuzumab) is not clinically effective.

The same principles for targeting of HER2 positive, HER2 positive /Herceptin (trastuzumab) resistant metastatic breast cancers and breast cancers with intermediate expression of HER2 also apply to other HER2 overexpressing cancers including; ovarian, certain uterine cancers, pancreatic cancers and bladder cancer.

Herceptin (trastuzumab) is indicated for the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinomas.

If these preclinical properties translate into the clinic, GBR 1302 would constitute an innovative treatment for HER2 positive cancers that is potentially superior to the current established monoclonal antibody treatments, Herceptin (trastuzumab), Perjeta (pertuzumab) and Kadcyla (trastuzumab emtansine)

BEAT™ (**B**i-specific **E**ngagement by **A**ntibodies based on the **T** cell receptor) is Glenmark's technology for production of bi-specific antibodies. Engaging two targets with one bi-specific antibody is a novel concept to design new therapeutics. For the past 20 years, bi-specific antibodies have been a challenge to the industry since most bi-specific 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 GBR 1302 is the first drug candidate based on this breakthrough antibody engineering technology.

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 (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 2 clinical trials in the US. The second monoclonal antibody, GBR 900 targets the TrkA receptor for chronic pain and is currently in clinical Phase 1. 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 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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