Glenmark Pharmaceuticals’ Experimental GBR 1302-BEAT™ Demonstrates Potent Anti-Tumor Activity in Preclinical Data Presented at the ESMO Symposium on Immuno-Oncology

An HER2xCD3 bi-specific antibody, GBR 1302 is the company’s first compound based on Glenmark’s proprietary BEAT™ platform to move into clinic

- GBR 1302 shows efficient, rapid and complete cytotoxic potential against HER2+ overexpressing tumor cells in preclinical studies
- GBR 1302 suppressed tumor growth, demonstrating improved efficacy, in HER2-positive tumor xenograft models

MAHWAH, N.J., November 4, 2016 – Glenmark Pharmaceuticals, a global pharmaceutical company, today announced preclinical findings suggesting that GBR 1302 is efficient at eliminating tumor cells and has potential for a large therapeutic window. Unlike current HER-2 targeting therapies, GBR 1302 targets both human CD3ε and HER2 and is designed to effectively recruit cytotoxic T lymphocytes against HER2 positive cancer cells, bringing them in close proximity to the tumor cells.

These findings were presented today in an oral presentation at the 4th ESMO (European Society of Medical Oncology) Symposium on Immuno-Oncology in Lausanne, Switzerland.

“The ability of GBR 1302 to more efficiently and rapidly destroy HER2+ overexpressing cancer cells is particularly encouraging for patients battling breast, gastric, esophageal, ovarian and endometrial cancers, among others,” said Kurt Stoeckli, president and Chief Scientific Officer at Glenmark. “These cancers are particularly difficult to treat and demand more effective treatments with better outcomes. We look forward to developing GBR 1302 further and expanding our BEAT™ technology to offer vital options for patients in whom monospecific, single-agent monoclonal antibodies aren’t sufficient.”

Results of an in vitro study showed potential for a large therapeutic window for GBR 1302 in destroying HER2+ cancer cells compared with normal cells. According to the data, the compound kills tumor cells at concentrations one thousand-fold lower than was found to kill cells expressing normal levels of HER2, such as cardiomyocytes, a surrogate for organ damage. The eradication of tumor cells seen with GBR 1302 was greater than with trastuzumab or pertuzumab, the antibodies currently approved for patients with HER2+ disease. Additionally, GBR 1302 did not significantly activate T cells in the absence of target cell engagement, a key requirement to treat patients safely.

The company is currently recruiting patients for this Phase 1 study in Germany and plans to expand the clinical trial program to the U.S. The design for the Phase 1 Study of GBR 1302 in subjects with HER2+ cancers will also be featured in a poster presentation at this meeting.
About BEAT™ Technology
BEAT™ (Bi-specific Engagement by Antibodies based on the T cell receptor) is Glenmark's technology for production of bi-specific antibodies (bsAbs). Engaging two targets with one bi-specific antibody is a novel approach to target cancer cells, in this case, by the redirection of killer T cells. However, it has been difficult to produce large amounts of bsAbs in the past. With the BEAT™ technology, Glenmark's scientists have been able to efficiently assemble and manufacture bi-specific molecules on an industrial scale. GBR 1302 is the first compound in human trials based on this breakthrough antibody engineering technology.

Glenmark's Immuno-Oncology Pipeline
In addition to GBR 1302, Glenmark’s expanding oncology portfolio of biologics includes GBR 1342 (CD38xCD3 bispecific antibody), the planned second clinical candidate based on BEAT™ technology, that targets CD38, potentially in multiple myeloma and other malignancies of hematopoietic origin. The third BEAT™ antibody in Glenmark’s pipeline is GBR 1372 (EGFRxCD3) which has demonstrated activity against EGFR expressing cancer cell lines independent of their RAS mutation, which can confer resistance to targeted (EGFR) treatments.

About Glenmark Pharmaceuticals
Glenmark Pharmaceuticals Ltd. (GPL) is a global innovative pharmaceutical company with operations in more than 80 countries. Glenmark has a diverse pipeline with several compounds in various stages of clinical development primarily focused in the areas of respiratory disease, oncology and immunology. Headquartered in Mumbai, India, Glenmark has improved the lives of millions of patients by offering safe, affordable medications for nearly 40 years. For more information visit www.glenmarkpharma.com/usa.

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