

Press Release

For Immediate Release

Glenmark Pharmaceuticals Receives FDA Clearance of IND for GBR 1302-BEAT™ Phase I Trial

Company to Initiate Phase I Clinical Study in Patients with HER2+ Cancer in 1Q 2017

Mahwah, NJ; January 3, 2016: Glenmark Pharmaceuticals, a global pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) cleared the Company's Investigational New Drug (IND) application to initiate a phase I study of its lead candidate, GBR 1302-BEAT™, in patients with HER2+ cancers. The company plans to expand the ongoing phase I clinical study to include sites in the United States for this potential first-in-class treatment, a humanized, bispecific monoclonal antibody targeting HER2 and CD3, based on the BEAT™ (Bi-specific Engagement of Antibodies based on the T cell receptor) technology platform.

Preclinical studies suggest GBR 1302 may have activity against a range of HER2-expressing tumor types, including breast, gastric and other cancers. Some of these findings were recently presented in an oral and poster presentation at the 4th ESMO (European Society of Medical Oncology) Symposium on Immuno-Oncology in Lausanne, Switzerland in November ([ESMO Press Release](#)).

“We believe GBR 1302 may have utility across a broad range of HER2+ tumor types. Data from preclinical studies are very encouraging”, said Fred Grossman D.O., President and Chief Medical Officer at Glenmark Pharmaceuticals Inc. “Based on its novel mechanism of redirecting T cells to HER2+ cancer cells, GBR 1302 has the potential to become an important therapy for previously treated and, eventually, newly diagnosed HER2+ tumors.”

About the Clinical Study

The phase I safety study is being conducted in two parts – dose escalation and expansion. The first part evaluates patients with previously treated HER2+ tumors to determine the safety and tolerability to maximum tolerated dose, as well as the pharmacokinetics and preliminary anti-tumor activity. The second part of the study is an expansion study of the same population treated at the maximum tolerated dose to determine early proof-of-concept. Patients in Germany are currently being treated in the dose escalation part of the study.

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 bispecific antibody is an approach to target cancer cells, in this case, by the redirection of cytotoxic T cells. With the BEAT™ technology, Glenmark's scientists have been able to overcome past production obstacles encountered with bsAbs and efficiently assemble and manufacture these molecules on an industrial scale. GBR 1302 is the first compound based on this breakthrough antibody engineering technology in human trials.

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 oncology, respiratory disease, and dermatology. Headquartered in Mumbai, India, and U.S. headquarters in Mahwah, NJ. Glenmark has improved the lives of millions of patients by offering safe, affordable medications for nearly 40 years. The BEAT™-based antibodies are researched and are manufactured at Glenmark's facility in Switzerland, and clinical development is directed from the Glenmark office in New Jersey, USA. For more information visit www.glenmarkpharma.com/usa.

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For further information, please contact:

Media Contact: An Phan (201) 778-3272