

Press Release For Immediate Release

# Glenmark Pharmaceuticals to Initiate Clinical Study for GBR 1342, Second Investigational New Drug from Immuno-Oncology Portfolio

### First-in-human study for GBR 1342 to begin in patients with multiple myeloma

Mumbai, India; May 16, 2017: 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 1 study of GBR 1342, a humanized, bispecific monoclonal antibody (bsAb) being studied for the treatment of multiple myeloma in patients who have received prior therapies. GBR 1342 is designed to activate the patient's immune system by redirecting immune cells towards tumor tissue, which may lead to targeted destruction of tumors. It is based on Glenmark's proprietary BEAT® (Bispecific Engagement by Antibodies based on the T cell receptor) technology platform.

"This is an exciting time for Glenmark as our flagship biotechnology platform and antibody science are beginning to become a reality for patients, now that we have a second oncology candidate entering clinical trials," said Kurt Stoeckli, President and Chief Scientific Officer at Glenmark Pharmaceuticals. "While there is still significant development ahead, these steps signify that Glenmark's investment in discovery and development of biologics is rapidly progressing."

The first-in-human Phase 1 study of GBR 1342 will enroll subjects with multiple myeloma who have exhausted available therapies. The study is being conducted in two parts: the first part is a dose escalation to determine the safety profile and maximum tolerable dose; the second is an expansion cohort treated at maximum tolerable dose to further investigate the safety profile and preliminary efficacy of GBR 1342.

GBR 1342 simultaneously engages CD38, a proven target in multiple myeloma, and the CD3 molecule on T cells. GBR 1342 is also being considered for the treatment of other malignancies.

### About Glenmark's Immuno-Oncology Pipeline and BEAT® Technology

Glenmark's oncology pipeline currently includes four candidates being studied in a wide range of tumor types. These include three bispecific monoclonal antibodies (bsAbs). GBR 1302, a HER2xCD3 bsAb, is being studied for the treatment of HER2+ cancers; GBR 1342, a CD38XCD3 bsAb, is being studied for the treatment of multiple myeloma and potentially other malignancies; and GBR 1372, an EGFRxCD3 bsAb, has demonstrated activity against EGFR expressing cells from resistant and refractory tumors. Glenmark's expanding oncology portfolio of biologics will include GBR 8383, an antibody-based agonist targeting OX40R, which is being studied for the treatment of multiple tumor types.

BEAT® (<u>B</u>ispecific <u>E</u>ngagement by <u>A</u>ntibodies based on the <u>T</u> cell receptor) is Glenmark's proprietary technology for the production of bsAbs. With BEAT® technology, Glenmark's scientists have been able to overcome past production obstacles encountered with bsAbs and efficiently assembled and manufactured these molecules with low immunogenicity potential on an industrial scale. Preclinically, BEAT® bsAbs have demonstrated the potential for safer, more controlled and localized activity in comparison to the broader systemic responses seen with many currently approved therapeutic antibodies. Additionally, BEAT® bsAbs structural similarity to naturally-occurring antibodies may result in an increased half-life compared to currently approved bispecific therapeutic antibodies and a decreased likelihood the body will identify the BEAT® bsAb as a foreign substance. GBR 1302, GBR 1342 and GBR 1372 are based on BEAT® technology.

## Glenmark Pharmaceuticals Ltd.



#### **About Glenmark Pharmaceuticals**

Glenmark Pharmaceuticals Ltd. (GPL) is a global innovative pharmaceutical company with operations in more than 50 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. Glenmark has improved the lives of millions of patients by offering safe, affordable medications for nearly 40 years. For more information, visit <a href="https://www.glenmarkpharma.com">www.glenmarkpharma.com</a>.

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