

Press Release - For Immediate Release

Glenmark Pharmaceuticals Presents Preliminary Biomarker Data on GBR 1302, a HER2xCD3 Bispecific Monoclonal Antibody, at the ASCO-SITC Clinical Immuno-Oncology Symposium

GBR 1302 is Glenmark's lead immuno-oncology agent based on the proprietary BEAT® bispecific antibody engineering platform

Mumbai, India; January 25, 2018: Glenmark Pharmaceuticals, a global pharmaceutical company, today announced a presentation of preliminary biomarker findings from a Phase 1 study of GBR 1302 (NCT02829372), an investigational bispecific antibody, at the ASCO-SITC Clinical Immuno-Oncology Symposium in San Francisco. GBR 1302 is based on Glenmark's proprietary BEAT® platform and simultaneously targets HER2 and the CD3 T cell co-receptor. HER2 is overexpressed in a variety of solid tumors and is a validated therapeutic target. This first-in-human study is ongoing and enrolling adults with progressive HER2-positive solid tumors who have not responded to available treatment options. The study is evaluating the safety and tolerability of GBR 1302, and exploring its anti-tumor activity.

"The discovery of agents targeting HER2 has greatly improved the treatment of a variety of cancers where it is overexpressed," said Kurt Stoeckli, President and Chief Scientific Officer at Glenmark Pharmaceuticals. "Investigational treatments like bispecific antibodies that target a broad spectrum of HER2 expression levels on a variety of tumor tissues while simultaneously engaging tumor-infiltrating T cells have the potential to advance the treatment of these tumors, and may fulfill a substantial unmet medical need. We are pleased to share this early data characterizing the clinical activity of GBR 1302 at the ASCO-SITC symposium."

Patients enrolled in the study receive intravenous GBR 1302 on Day 1 and Day 15 in 28-day treatment cycles at escalating doses until maximum-tolerated dose is achieved. Preliminary biomarker data demonstrate modulation of peripheral T cell populations and cytokines. Some subjects treated at the higher doses experienced cytokine release syndrome, which was mild and transient. Dose escalation is ongoing. These data will be presented during the Trials in Progress Poster Session on January 25th from 11:30 AM – 1:00 PM and 5:30 – 6:30 PM in San Francisco, CA.

"These preliminary data for GBR 1302 tell us the spikes in peripheral blood cytokines and a drop in T cell levels suggest the potential for T cell activation," said lead study investigator Martin Wermke, MD, University Hospital Carl-Gustav-Carus, Dresden, Germany. "As such, we are encouraged by these initial findings and look forward to continuing this important study which will help us more fully understand the science behind the mechanism of action and the potential for clinical activity."

About Glenmark's Oncology Pipeline and Proprietary BEAT® Technology

Glenmark's pipeline currently includes three immuno-oncology candidates being studied in a wide range of tumor types. These include three bispecific monoclonal antibodies (bsAbs). GBR 1302, a HER2xCD3 bsAb, targets HER2 expressing tumors including those not responsive to standard of care; GBR 1342, a CD38XCD3 bsAb targeting CD38 positive tumors including hematologic malignancies and solid tumors; and GBR 1372, an EGFRxCD3 bsAb targeting EGFR positive tumors including those resistant to standard of care.

BEAT® (Bispecific Engagement by Antibodies based on the T 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 can efficiently manufacture these molecules at clinical and commercial scale. Preclinically, BEAT® bsAbs demonstrate the potential for more potent activity compared to existing therapeutic antibodies. Additionally, structural similarity to naturally-occurring antibodies may result in a normalized IgG half-life and less immunogenicity. GBR 1302, GBR 1342 and GBR 1372 are based on BEAT® technology.

About Glenmark Pharmaceuticals

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical organization. It is ranked among the top 75 Pharma & Biotech companies of the world in terms of revenue (SCRIP 100 Rankings published in the year 2018). 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 focused in the areas of oncology, dermatology and respiratory.

The company has a significant presence in the branded generics markets across emerging economies including India. Glenmark has 16 manufacturing facilities across five countries and has six 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, Asia-Pacific, Latin America and India. For more details, log onto www.glenmarkpharma.com