

Press Release – For Immediate Release

Glenmark Pharmaceuticals Announces New Data on GBR 1302, a HER2xCD3 Bispecific Antibody, Presented at the ESMO Immuno-Oncology Congress 2018

GBR 1302 is Glenmark's leading investigational immuno-oncology agent and is based on Glenmark's proprietary BEAT® (Bispecific Engagement by Antibodies based on the T cell receptor) platform

Paramus, NJ; December 14, 2018 – Glenmark Pharmaceuticals, a global innovative pharmaceutical company, today announced the presentation of new pharmacokinetic data from the ongoing Phase 1 trial of GBR 1302, a HER2xCD3 bispecific antibody, at the European Society for Medical Oncology Immuno-Oncology (ESMO-IO) Congress 2018 in Geneva, Switzerland. GBR 1302 is Glenmark's lead immuno-oncology candidate and is currently in a first-in-human trial to determine maximum tolerated dose (MTD) in an all-comers population of patients with a variety of HER2 positive cancers. These Phase 1 data will inform dosing regimen optimization of GBR 1302.

“Due to the anticipated potency and limited clinical experience with T-cell redirecting bispecific antibodies, determining the optimal dosing regimen for novel investigational medicines like GBR 1302 is key to unlocking its potential,” said Mahboob Rahman, President and Chief Medical Officer at Glenmark Pharmaceuticals. “An innovative method of quantification was developed to facilitate the measurement of very low systemic concentrations of GBR 1302 in the clinical study. These findings provide insights into the pharmacokinetics of GBR 1302 and inform dosing regimen decisions to maximize its potential effectiveness for patients with HER2 positive cancers.”

A low starting dose of 1 ng/kg was selected for the first-in-human Phase 1 study of GBR 1302, and dose escalation continued in small increments using a biweekly regimen. Glenmark developed and utilized a novel hybrid immunocapture-LC/MS/MS method for quantification of GBR 1302 in human serum to overcome the difficulty of generating pharmacokinetic data at the low doses administered in the study.¹

Pharmacokinetic profiles of GBR 1302 were observed from doses of 30 ng/kg and beyond. In general, maximum concentration (C_{max}) was observed close to the end of infusion, after which serum concentrations declined bi-exponentially, with a mean terminal half-life of approximately four to seven days. Both, C_{max} and exposure (AUC_{0-t}), showed near dose-proportional increases up to 750 ng/kg, the highest dose evaluated in the Phase 1 trial thus far.¹

Consistent with the half-life findings, Glenmark plans to initiate a study of GBR 1302 in HER2 positive breast cancer patients with a weekly dosing regimen.

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 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 glenmarkpharma-us.com.

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References:

1. Gudi G et al. Preliminary pharmacokinetic results from a Phase 1 study of GBR 1302 in patients with HER2 positive cancers. ESMO Immuno-Oncology Conference. December 2018.