

Press Release – For Immediate Release

Glenmark Pharmaceuticals Announces Decision to Launch Phase 1 Trial in Solid Tumors for its CD38xCD3 Bispecific Antibody GBR 1342 Based on Human Translational Data

GBR 1342 is one of three investigational immuno-oncology agents based on Glenmark's proprietary BEAT® platform

Paramus, NJ; November 7, 2018 – Glenmark Pharmaceuticals, a global pharmaceutical company, today announced the decision to launch a Phase 1 trial in solid tumors for its CD38xCD3 bispecific antibody GBR 1342. The decision is driven by recent findings derived from a non-interventional human study utilizing a clinically validated CANscript™ platform. GBR 1342 is based on Glenmark's proprietary BEAT® platform and simultaneously targets CD38 and the CD3 T cell co-receptor. CD38 is an antigen known to be implicated in hematological malignancies as well as some solid tumors.¹ The company intends to file an Investigational New Drug (IND) application for GBR 1342 in solid tumors and initiate a clinical trial in 2019.

“Our work with innovative immunotherapeutics such as T cell re-directing bispecific antibodies necessitates detailed analyses to fully-understand and assess the potential opportunities presented by the candidates in our pipeline,” said Kurt Stoeckli, President and Chief Scientific Officer at Glenmark Pharmaceuticals. “We are pleased to report that predictive analytics have generated new insights on response rates which inform further clinical development of GBR 1342 in a variety of solid tumor types, both as monotherapy and in combination therapy.”

The decision to expand clinical development of GBR 1342 was based on a recently completed *ex vivo* translational study in multiple solid tumors utilizing the clinically validated CANscript™ platform,² where treatment with GBR 1342 revealed predictive responses in various tumor types. CANscript™ is a completely human, autologous human tumor platform that integrates an algorithm-driven strategy to predict clinical responses. Glenmark plans to submit these data, along with findings on the mechanism of action, for presentation at upcoming scientific meetings and publication in a peer-reviewed journal. An ongoing first-in-human, open-label, Phase 1 trial of GBR 1342 in multiple myeloma (NCT03309111), is assessing the safety and tolerability of increasing doses of GBR 1342, and will also evaluate biomarkers, immunogenicity, and additional measures of disease 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 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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¹ [Immunol Rev.](#) 2016 Mar; 270(1): 95–112.

² [Nat Commun.](#) 2015 Feb; 6:6169