

Press Release

For Immediate Release

Glenmark receives acceptance from U.S. FDA on its IND application for GRC 54276 to proceed with a Phase 1/2, first-in-human clinical study of the molecule for the treatment of patients with advanced solid tumors and lymphomas

Mumbai, India; March 16, 2023: Glenmark Specialty SA, the subsidiary of Glenmark Pharmaceuticals Ltd., an innovation-driven, global pharmaceuticals company received acceptance from the U.S. Food and Drug Administration (FDA) on its Investigational New Drug (IND) application for GRC 54276 to proceed with a Phase 1/2, first-in-human, clinical study of GRC 54276 for the treatment of patients with advanced solid tumors and lymphomas.

GRC 54276 is an orally available, small molecule hematopoietic progenitor kinase 1 (HPK1) inhibitor developed by Glenmark. HPK1-regulated functions are involved in nearly every step of the cancer-immunity cycle making it an attractive target for immuno-oncology. By inhibiting HPK1, GRC 54276 is designed to potentially enhance the patient's own immune system to fight cancers.

A Phase 1/2 multicenter, open-label study to evaluate the safety, tolerability, pharmacokinetics and preliminary anti-tumor activity of GRC 54276 is currently underway in India. GRC 54276 is being studied as monotherapy or in combination with Anti PD-1 or Anti PDL-1 therapy in adults with advanced solid tumors and lymphomas. To date, 16 patients with various type of advanced cancers have been enrolled in this ongoing study in India, and company plans to expand the study at ex-India research sites in the subsequent months.

“Now that the FDA has accepted our IND application, we look forward to initiating the ongoing Phase 1/2 study at the US sites. This is an important milestone for Glenmark as we continue to advance our oncology pipeline. We are excited about the prospects of what this new class of immune-oncology medicines may mean for patients in need,” said Nikhil Amin (MD), Chief scientific officer and President, innovative Medicine Group, Glenmark Pharmaceuticals Ltd.

---End---

About Glenmark Pharmaceuticals Ltd.

Glenmark Pharmaceuticals Ltd. (BSE: 532296 | NSE: GLENMARK) is an innovation-driven, global pharmaceutical company with a presence across Branded, Generics, and OTC segments; with a focus on therapeutic areas of respiratory, dermatology and oncology. The company has 10 world-class manufacturing facilities spread across 4 continents, and operations in over 80 countries. In Vivo/Scrip 100 positions Glenmark amongst the Top 100 Companies Ranked by R&D and Pharmaceutical Sales, 2021; while Generics Bulletin/In Vivo places it in the Top 50 Generics and Biosimilars Companies Ranked by Sales, 2021. The company has been Great Place To Work® Certified™ in India, in 2023. Glenmark has impacted over 2.6 million lives over the last decade through its CSR interventions. For more information, visit www.glenmarkpharma.com. Follow us on LinkedIn (Glenmark Pharmaceuticals) and Instagram (glenmark_pharma).

For more information, please contact

Udaykumar Murthy | +91 9960377617 | corpcomm@glenmarkpharma.com