

Glenmark Advances Multi-Country Phase 3 Clinical Trial of Trastuzumab rezetecan in Platinum-Resistant Ovarian Cancer

Study aligned with Hengrui Pharma's ongoing parent Phase 3 trial in China

India becomes the first country in Glenmark's licensed markets to receive regulatory approval for Phase 3 clinical trial extension

Additional patient enrollment planned in Australia and South Korea, subject to regulatory approval

Mumbai, India, 02 July, 2026 – Glenmark Specialty S.A, a wholly owned subsidiary of Glenmark Pharmaceuticals Ltd. (Glenmark) announced the advancement of its multi-country Phase 3 clinical trial for Trastuzumab rezetecan (SHR-A1811), a HER2-targeted antibody drug conjugate (ADC), for patients with platinum-resistant ovarian cancer (PROC).

India will serve as the first country in Glenmark's licensed markets to initiate patient enrollment for the Phase 3 clinical trial, following the approval of Drugs Controller General of India (DCGI). Glenmark also plans to enroll patients in Australia and South Korea, subject to regulatory approvals.

The study is aligned with Jiangsu Hengrui Pharmaceuticals Co. Ltd.'s ongoing parent Phase 3 trial in China. Glenmark aims to generate clinically relevant data across broader and more diverse patient populations, supporting the development of Trastuzumab rezetecan across Glenmark's licensed markets. The randomized, controlled, multi-centre, Phase 3 trial is designed to evaluate the efficacy, safety, and pharmacokinetics of Trastuzumab rezetecan in patients with HER2-expressing platinum-resistant ovarian cancer, a difficult-to-treat disease where treatment options remain limited, and outcomes continue to be poor. Conducting the trial across multiple geographies is expected to support the generation of evidence from diverse patient groups and strengthen the clinical data package for the therapy across Glenmark's licensed markets.

Commenting on the announcement, Dr. Monika Tandon, Global Head of Clinical Development, Glenmark Pharmaceuticals Limited, said, "Advancing this pivotal Phase 3 trial marks an important step in Glenmark's journey to build a differentiated oncology pipeline for global markets. Platinum-resistant ovarian cancer remains an area of significant unmet need, and the initiation of patient enrollment in India, with additional countries planned, reflects our commitment to developing novel targeted therapies for patients with hard-to-treat cancers and limited treatment options. This study also strengthens our ability to generate clinically relevant evidence across diverse populations."

Ovarian cancer remains one of the most challenging gynecologic malignancies globally. It is the eighth¹ most common cancer among women worldwide. India carries a significant burden, ranking among the countries with the highest number of ovarian cancer cases and deaths globally. Many patients with advanced ovarian cancer treated with available platinum-based

therapies develop recurrence and subsequently platinum resistance. This underscores the need for continued clinical development of targeted therapies that may improve treatment options for patients with advanced and resistant disease.

In September 2025, Glenmark entered into an exclusive collaboration and license agreement with Jiangsu Hengrui Pharmaceuticals Co., Ltd. ("Hengrui Pharma") for Trastuzumab rezetecan (SHR-A1811), securing rights to develop and commercialize the asset across multiple markets. Under the agreement, Glenmark holds exclusive rights worldwide excluding Mainland China, the Hong Kong SAR, the Macao SAR, Taiwan Region, USA, Canada, Europe, Japan, Russia, Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan and Uzbekistan.

¹[PubMed](#)

About Trastuzumab Rezetecan

Trastuzumab rezetecan (SHR-A1811) is a HER2-targeted first-in-class antibody-drug conjugate (ADC) developed by Hengrui Pharma to address the challenges posed by HER2-overexpressing tumors, which are prevalent in various cancer types, including breast, gastric and colorectal cancers.

In May 2025, it has been conditionally approved in China and is now marketed for the treatment of adult patients with unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) who have HER2 (ERBB2) activating mutations and have received at least one prior systemic therapy. This marked the first China-developed ADC approved for HER2-mutated NSCLC.

Subsequently, in September 2025, the marketing authorization application for a new breast cancer indication was accepted for review by China's National Medical Products Administration (NMPA) and granted Priority Review designation. The application was approved in March 2026 for the treatment of patients with HER2-positive second-line (2L) breast cancer.

In February 2026, Hengrui Pharma also filed a biologics license application (BLA) for the treatment of HER2-positive advanced colorectal cancer.

To date, Trastuzumab rezetecan has been included in the NMPA's Breakthrough Therapy Designation list for nine indications, covering NSCLC, breast cancer, gastric or gastroesophageal junction adenocarcinoma, colorectal cancer, biliary tract cancer, and gynecologic malignancies.

About Glenmark Pharmaceuticals Ltd.

Glenmark Pharmaceuticals Ltd. (BSE: 532296 | NSE: GLENMARK) is a global, research-led pharmaceutical company with a unique focus on innovation and accessibility. We pioneer transformative breakthrough therapies that aim to redefine treatment while expanding access to high-quality and affordable medicines for patients around the world. With 11 world-class manufacturing facilities across four continents, supported by six cutting-edge R&D centres, and a commercial footprint in 80+ countries, we deliver a diversified portfolio across branded, innovative, generics, and consumer health products, with a focus on respiratory, dermatology, and oncology. Scrip 100 positions Glenmark among the Top 100 biopharmaceutical companies globally by pharmaceutical sales for 2024. For more information, visit www.glenmarkpharma.com.

For more information, please contact:

Akhila Natarajan | mediarelations@glenmarkpharma.com | +91 22 4018 9999
Adfactors PR | Jigyasha Sharma | glenmark.ihcp@adfactorspr.com | + 91 9819514233