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GSK presents first global data for Ris-Rez in extensive-stage small cell lung cancer

- 61% overall response rate in phase Ib trial
- Results build on positive pivotal data in Chinese patients
- Data supports accelerated Ris-Rez development, including in ongoing global phase III trial in ES-SCLC

GSK plc (LSE/NYSE: GSK) today announced the first global data for risvutatug rezetecan (Ris-Rez), its investigational B7-H3-targeted antibody-drug conjugate (ADC), in patients with relapsed extensive-stage small cell lung cancer (ES-SCLC). Results from the phase Ib dose-optimisation portion of the EMBOLD PanTumour-101 trial showed positive anti-tumour activity and a manageable safety profile, adding to recently reported positive phase III data in patients with SCLC in China.¹

In the trial, Ris-Rez achieved a confirmed objective response rate (ORR) of 61% among evaluable patients at the 8 mg/kg dose (n=11/18; 95% CI: 35.7-82.7), compared with 32% at the 6 mg/kg dose (n=7/22; 95% CI: 13.9-54.9). These findings will be presented in a poster session at the European Society for Medical Oncology (ESMO) Congress 2026 in Madrid, Spain. Along with data from Hansoh's phase III ARTEMIS-008 study in SCLC, this data supported selection of the 8 mg/kg dose currently being evaluated in GSK's global phase III EMBOLD SCLC-301 study.

Hesham Abdullah, Senior Vice President, Global Head of Oncology, R&D, GSK said, "Today's first global data for Ris-Rez build on the statistically significant overall survival benefit recently reported in Hansoh's pivotal Chinese trial. As the data for Ris-Rez continues to grow, we remain focused on accelerating development in extensive-stage small cell lung cancer, where patients often relapse quickly and urgently need more treatment options."

The safety profile was manageable across both dose levels at a median follow-up of 100.5 days. Grade 3 or higher treatment-related adverse events (TRAEs) were observed in 42% of patients receiving 8 mg/kg and 15% of those receiving 6 mg/kg, with haematological events being the most common. The overall rate of interstitial lung disease (ILD) was low (2%; 1 out of 50 patients) and the case was moderate (grade 2).

Hye Ryun Kim, MD, PhD, Division of Medical Oncology, Yonsei Cancer Center, and a study investigator in the EMBOLD PanTumour-101 study, said, "Extensive-stage small cell lung cancer remains one of the most aggressive cancers we treat, with five-year survival rates typically in the single digits. Patients whose disease relapses often have limited options, and current therapies can be difficult to tolerate. The response rates and manageable safety profile observed with Ris-Rez are encouraging and support its ongoing development in this setting."

These data will be presented alongside a broader set of findings from the EMBOLD programme at ESMO 2026, including global dose-escalation results from EMBOLD PanTumour-101, an analysis of ILD across the Ris-Rez early clinical programme, and the design of the global phase III EMBOLD SCLC-301 study. Real-world evidence from the RESONANCE study further demonstrates the complexity of treatment decision-making after relapse in ES-SCLC and highlights the absence of a clear treatment standard in later lines of therapy. Together, these findings contribute to the growing body of evidence for Ris-Rez and reflect GSK's focus on advancing targeted medicines where significant patient need and scientific opportunity remain.



About EMBOLD PanTumour-101

EMBOLD PanTumour-101 (NCT06551142) is a global, open-label phase Ia/b study evaluating the safety, tolerability and clinical activity of Ris-Rez monotherapy in adult patients with advanced or metastatic solid tumours. In the phase Ib dose-optimisation portion of the study, patients with relapsed (2L+) extensive-stage small cell lung cancer were randomised to receive Ris-Rez 6 mg/kg or 8 mg/kg intravenously every three weeks until disease progression, unacceptable toxicity, loss to follow-up or death. The analysis presented at ESMO 2026 included 50 patients who had received a median of two prior therapies. The study population included patients with prior topoisomerase-1 inhibitor or tarlatamab exposure, as well as patients with brain or liver metastases. Enrolment in the phase Ib dose-optimisation portion of the trial was still ongoing at data cut-off, and longer follow-up will be needed to further characterise the durability of response.

About risvutatug rezetecan

Ris-Rez is a novel investigational antibody-drug conjugate targeting the B7-H3 protein, which is highly expressed in more than 10 solid tumour types, supporting GSK's ambition to develop it across more than 40 indications by 2040. GSK acquired exclusive worldwide rights (excluding China's mainland, Hong Kong, Macau, and Taiwan) from Hansoh Pharma to progress clinical development and commercialisation of Ris-Rez. More than 1,000 patients have received Ris-Rez as part of GSK's global EMBOLD clinical trial programme, which includes phase III trials in late-line extensive-stage small cell lung cancer (ES-SCLC) and metastatic castration-resistant prostate cancer (mCRPC), with additional upcoming phase III trials planned in early-line SCLC and chemo-naïve mCRPC. Ris-Rez has received several global regulatory designations to date, including orphan drug designations in the US, Japan and the EU for SCLC, and Breakthrough Therapy Designation in the US and Priority Medicines (PRIME) Designation from the EMA for relapsed or refractory ES-SCLC, among others.^{2,3,4,5,6}

About small cell lung cancer

Small cell lung cancer (SCLC) is associated with rapid progression and accounts for approximately 10-15% of all lung cancer diagnoses worldwide.⁷ SCLC is characterised by early metastatic spread, frequent relapse and poor prognosis.⁷ Approximately 70% of patients with SCLC are diagnosed with extensive-stage disease (ES-SCLC), meaning the cancer has spread throughout one or both lungs and/or to other parts of the body.^{7,8} Median overall survival for patients with ES-SCLC treated with current standard-of-care therapies is approximately 12 to 13 months.⁸ Despite advances in treatment, outcomes for patients with ES-SCLC remain poor and risk of disease progression or recurrence remains high, underscoring the need for new therapies that can improve outcomes for patients facing this aggressive cancer.

About GSK in oncology

GSK is focused on developing differentiated medicines for cancers where patients continue to face poor outcomes, treatment resistance, limited options or significant treatment burden. We focus where advances in science and technology offer the greatest opportunity to improve outcomes across haematological, lung, gastrointestinal, genitourinary and gynaecological cancers. Across multiple modalities, including targeted small molecules, antibody-drug conjugates (ADCs) and immunotherapies, GSK applies deep expertise in cancer biology and immune system science to develop differentiated medicines designed to deliver durable responses, overcome resistance and reduce treatment burden.

About GSK

GSK is a global biopharma company with a purpose to unite science, technology and talent to get ahead of disease together. Find out more at www.gsk.com.

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GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2025, and GSK's Q2 Results for 2026.

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