# Press release

For media and investors only

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# Ris-Rez reduced risk of death by 54% versus topotecan in patients with relapsed small cell lung cancer in China

- Patients receiving Ris-Rez lived a median of 18.5 months versus 10.3 months with comparator
- Longer survival achieved with fewer severe treatment-related side effects versus comparator
- GSK is developing Ris-Rez in small cell lung cancer and other solid tumours outside China

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GSK plc (LSE/NYSE: GSK) licensor Hansoh Pharmaceutical Group Co., Ltd., today announced positive overall survival (OS) data from ARTEMIS-008, its pivotal phase III trial in China evaluating the B7-H3-targeted antibody-drug conjugate (ADC) risvutatug rezetecan (Ris-Rez) versus topotecan in patients with relapsed small cell lung cancer (SCLC) whose disease progressed following platinum-based first-line therapy. These results, first announced in July, are the first Phase III data to demonstrate an OS benefit for a B7-H3 ADC in any tumour type.

In the trial, Ris-Rez reduced the risk of death by 54% compared with topotecan, a commonly used treatment option following progression on first-line therapy, meeting the trial's primary endpoint after a median follow-up of 12.2 months (HR 0.46; 95% CI: 0.35-0.62, p<0.0001). Patients receiving Ris-Rez lived a median of 18.5 months (n=230) compared with 10.3 months for those receiving topotecan (n=231). These results were presented in a Presidential Symposium session at the 2026 World Conference on Lung Cancer (WCLC) in Seoul, South Korea.

**Hesham Abdullah, Senior Vice President, Global Head of Oncology, R&D, GSK said**, "These results add to the growing body of evidence for Ris-Rez and mark an important step forward for our lung cancer portfolio. The significant improvement in survival observed in this study, together with an encouraging safety profile, provide further momentum for GSK's global development of Ris-Rez across later-line and earlier treatment settings for small cell lung cancer."

The OS benefit observed was supported by improvements across key secondary efficacy endpoints. Median progression-free survival as assessed by an independent review committee (IRC) was 7.2 months versus 3.0 months (HR 0.33; 95% CI: 0.25-0.42); IRC-assessed objective response rate was 58.3% versus 12.6%; and IRC-assessed disease control rate was 90.4% versus 60.2% for Ris-Rez and topotecan, respectively.

Patients receiving Ris-Rez experienced fewer severe treatment-related side effects (TRAEs) than those receiving topotecan, with grade 3 or higher TRAEs occurring in 60.9% versus 78.2% of patients, respectively. The most common grade 3 or higher TRAEs with Ris-Rez were decreased neutrophils, decreased white blood cells, anaemia, decreased lymphocytes and decreased platelets. These haematologic TRAEs are considered manageable and consistent with the known side effects in this class of medicines.

**Jie Wang, M.D., Chair, Medical Oncology Department, National Cancer Center, Chinese Academy of Medical Sciences and Principal Investigator of the ARTEMIS-008 trial, said,** "Relapsed small cell lung cancer remains one of the most challenging cancers to treat, with few therapies delivering meaningful improvements in survival once the disease returns. In ARTEMIS-008, patients receiving Ris-Rez lived substantially longer while experiencing lower rates of severe treatment-related side effects. These findings suggest Ris-Rez could represent an important advance for patients."

GSK holds exclusive rights to develop and commercialise Ris-Rez outside mainland China, Hong Kong, Macau and Taiwan, and is advancing a broad global clinical development programme across lung cancer, prostate cancer and other solid tumours, including the phase III EMBOLD SCLC-301 trial in relapsed extensive-stage SCLC, with pivotal data expected next year.

**About ARTEMIS-008**
ARTEMIS-008 is Hansoh's multicentre, randomised, open-label, active-controlled phase III trial evaluating Ris-Rez versus topotecan in patients in China with limited- or extensive-stage SCLC whose disease progressed on or after first-line platinum-based therapy. Patients were randomised 1:1 to receive Ris-Rez 8.0 mg/kg every three weeks or topotecan 1.2 mg/m² on days 1–5 of each 21-day cycle. The primary endpoint is statistically significant and clinically meaningful improvement in overall survival. Secondary endpoints include progression-free survival, objective response rate, disease control rate, duration of response and safety.

**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. More than 1,000 patients have received Ris-Rez as part of GSK's global EMBOLD clinical trial programme, which includes a phase III trial in late-line extensive-stage small cell lung cancer (ES-SCLC), with additional upcoming phase III trials planned in early-line SCLC and metastatic prostate cancers. Ris-Rez has received several global regulatory designations to date, such as 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.[1, 2, 3, 4,5]

**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.[6] SCLC is characterised by early metastatic spread, frequent relapse and poor prognosis.[6] 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.[6,7] Median overall survival for patients with ES-SCLC treated with current standard-of-care therapies is approximately 12 to 13 months.[7] 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.

**GSK in oncology**
GSK's ambition in oncology is to help increase overall quality of life, maximise survival and change the course of disease, expanding from our current focus on blood and women's cancers into lung and gastrointestinal cancers, as well as other solid tumours. This includes accelerating priority programmes such as antibody-drug conjugates (ADCs) Ris-Rez targeting B7-H3 and Mo-Rez targeting B7-H4, and velzatinib, a highly selective KIT tyrosine kinase inhibitor.

GSK's focus in lung cancer is to develop medicines that can deliver durable responses, overcoming resistance and reducing treatment burden across small cell and non-small cell lung cancers. GSK's lung cancer portfolio is built on validated targets and modalities where we have growing expertise, including targeted small molecules and ADCs. This approach allows us to match the right therapeutic modality to the right target, tumour type and patient need – with the bold ambition to launch multiple new options in lung cancer over the next five years.

**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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**Cautionary statement regarding forward-looking statements**
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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