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GSK's licensor Hansoh Pharma announces positive phase III results for Ris-Rez in China patient population

- ARTEMIS-008, a phase III study conducted for China, met its primary endpoint of overall survival in advanced or relapsed small-cell lung cancer
- First positive phase III overall survival data for a B7-H3-targeted ADC in any tumour type
- GSK is advancing risvutatug rezetecan outside China across multiple tumour types, including lung cancer, prostate cancer and other solid tumours

GSK plc (LSE/NYSE: GSK) licensor Hansoh Pharmaceutical Group Co., Ltd. today announced that ARTEMIS-008, its pivotal phase III trial evaluating risvutatug rezetecan (Ris-Rez) in patients with advanced or relapsed small-cell lung cancer (SCLC), met its primary endpoint of overall survival (OS). In the trial, conducted in patients in China, Ris-Rez demonstrated statistically significant and clinically meaningful improvements in OS compared with the standard of care, topotecan. Consistent benefit was also observed across key secondary endpoints, including progression-free survival. These data will be used by Hansoh Pharma for regulatory submission in China.

These are the first positive phase III overall survival data reported for a B7-H3-targeted antibody-drug conjugate (ADC) in any tumour type. The safety profile is consistent with prior Ris-Rez findings, and no new safety signals were identified.

GSK holds exclusive global rights to develop Ris-Rez outside mainland China, Hong Kong, Macau and Taiwan. GSK's broad clinical development programme includes studies in lung cancer, prostate cancer and other solid tumours, including the global phase III EMBOLD SCLC-301 trial in relapsed extensive-stage small-cell lung cancer (ES-SCLC) with pivotal data expected next year.

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK said: "These results are an important milestone as the first positive phase III overall survival data for a B7-H3-targeted ADC in any tumour type. Together, with other data generated to date, they further support the potential of B7-H3 as a promising target across lung cancer and other solid tumours and reinforce our continued development of Ris-Rez to improve standard of care in areas of high unmet need."

Most patients with ES-SCLC relapse after initial therapy and have limited treatment options, poor prognosis and significant treatment burden.¹ B7-H3 is highly expressed in SCLC tumours^{2,3} and the positive results from ARTEMIS-008 add to the growing body of evidence supporting the encouraging clinical activity and manageable safety profile of Ris-Rez in patients with ES-SCLC.

About risvutatug rezetecan

Ris-Rez is a novel investigational B7-H3-targeted ADC composed of a fully human anti-B7-H3 monoclonal antibody covalently linked to a topoisomerase inhibitor payload. 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.

Regulatory designations received for Ris-Rez to date include orphan drug designations from the US Food and Drug Administration (FDA) and Japan's Ministry of Health, Labour and Welfare in SCLC and the European Medicines Agency (EMA) in a category of cancer that includes SCLC, called pulmonary neuroendocrine carcinoma; Priority Medicines (PRIME) Designation from the EMA for relapsed or refractory ES-SCLC; and Breakthrough Therapy

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Designations for relapsed or refractory ES-SCLC and relapsed or refractory osteosarcoma from the US FDA.^{4,5,6,7,8,9,10}

GSK in oncology

Our 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 gynaecologic cancers into lung and gastrointestinal cancers, as well as other solid tumours. This includes accelerating priority programmes such as antibody-drug conjugates targeting B7-H3 and B7-H4, and velizatinib, a highly selective KIT tyrosine kinase inhibitor.

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 Q1 Results for 2026.

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