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Ris-Rez reduced risk of disease progression or death by 67% versus chemotherapy in patients with relapsed osteosarcoma in China

- Patients receiving Ris-Rez remained progression-free for a median of 5.5 months versus 1.4 months with comparator
- Second positive phase III trial in China adds to growing body of late-stage evidence for Ris-Rez in different solid tumours
- GSK's global phase II trial is ongoing in advanced osteosarcoma and soft tissue sarcoma

GSK plc (LSE/NYSE: GSK) licensor Hansoh Pharmaceutical Group Co., Ltd., today announced positive results from its ARTEMIS-011 study, a pivotal phase III trial in China evaluating risvututug rezetecan (Ris-Rez) in patients whose osteosarcoma had progressed or relapsed after at least two prior lines of systemic therapy. The trial met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in progression-free survival (PFS) as assessed by an Independent Review Committee (IRC) versus chemotherapy.

In ARTEMIS-011, Ris-Rez reduced the risk of disease progression or death by 67% compared with chemotherapy, after a median follow-up of 7.1 months (HR, 0.33; 95% CI, 0.20-0.55; $p < 0.0001$). Median PFS was 5.5 months with Ris-Rez versus 1.4 months with chemotherapy. The late-breaking results were presented during a Presidential Symposium session at the European Society for Medical Oncology (ESMO) Congress 2026 and will support a regulatory submission by Hansoh in China.

Hesham Abdullah, Senior Vice President, Global Head of Oncology, R&D, GSK said, "This is Hansoh's second positive phase III study for Ris-Rez in China and adds to a growing body of evidence across multiple difficult-to-treat solid tumours. For patients with relapsed osteosarcoma, where treatment options are extremely limited, these findings are particularly important. The results will help inform GSK's global development programme, including our ongoing phase II trial in advanced osteosarcoma and soft tissue sarcoma."

In the trial, safety findings were consistent with prior findings in this tumour type. Grade 3 or higher treatment-related adverse events (TRAEs) occurred in 93% of patients receiving Ris-Rez at the 12 mg/kg dose and 83% in those receiving chemotherapy. The most common Grade 3 or higher TRAEs in both arms were haematologic events. TRAEs led to discontinuation in 4% of patients receiving Ris-Rez and 2% of patients receiving chemotherapy.

Lu Xie, Medical and Pediatric Oncologist for Sarcoma; Deputy Medical Director, Musculoskeletal Tumor Center; Clinical Associate Professor, Master Supervisor, Peking University and Principal Investigator of Hansoh's ARTEMIS-011 trial, said, "Osteosarcoma typically affects children and young adults, and for patients whose disease has returned or progressed following multiple treatments, there are no approved therapies and no clearly established standard of care. The improvement in progression-free survival observed with Ris-Rez adds important new evidence in a setting where advances have been difficult to achieve."

ARTEMIS-011 was conducted by Hansoh Pharma. GSK holds exclusive rights to develop and commercialise Ris-Rez outside mainland China, Hong Kong, Macau and Taiwan and is advancing a global clinical development programme across lung cancer, prostate cancer and other solid tumours. This includes the phase Ib/II EMBOLD Sarcoma-202 trial in previously treated unresectable advanced or metastatic sarcomas, including osteosarcoma.

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The study is designed to further characterise the benefit-risk profile of Ris-Rez, with data from ARTEMIS-011 helping to inform dose selection in a global population.

About osteosarcoma

Osteosarcoma is a rare cancer with a global incidence of approximately 3.4 cases per million people per year.¹ It mainly affects children and young adults and is the most common primary bone cancer, accounting for 20-40% of all bone cancers.² Following first-line chemotherapy, treatment options for patients with relapsed osteosarcoma are severely limited, with no clear standard of care available.³ After patients progress on two prior lines of treatment, options become even more limited, with no approved therapies.

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 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, such as orphan drug designations in the US, Japan and the EU for SCLC; Breakthrough Therapy Designation in the US and Priority Medicines (PRIME) Designation from the EMA for relapsed or refractory ES-SCLC; and Breakthrough Therapy Designation in the US for relapsed or refractory osteosarcoma, among others.

About ARTEMIS-011

ARTEMIS-011 is Hansoh Pharma's multicentre, randomised, open-label phase III trial evaluating Ris-Rez compared with chemotherapy (gemcitabine and docetaxel) in patients in China with osteosarcoma who had progressed or relapsed after at least two prior lines of systemic therapy. Patients were randomised 1:1 to receive Ris-Rez 12.0 mg/kg every 3 weeks on day 1 or gemcitabine 1,000 mg/m² on days 1 and 8 plus docetaxel 75 mg/m² on day 8 every 3 weeks. While an 8 mg/kg dose was used in the ARTEMIS-008 trial in small-cell lung cancer, a higher 12 mg/kg dose was selected for this trial to account for potential difficulty in penetrating bone tissue. The primary endpoint is Independent Review Committee (IRC)-assessed progression-free survival. Secondary endpoints are investigator-assessed overall survival, investigator-assessed PFS and safety, as well as IRC-assessed objective response rate (ORR), disease control rate and, duration of response (DOR).

About EMBOLD Sarcoma-202

EMBOLD Sarcoma-202 is a phase Ib/II study evaluating the efficacy and safety of Ris-Rez in global participants with previously treated unresectable advanced or metastatic sarcomas. The trial is designed to characterise the benefit-risk of Ris-Rez and inform the optimal dose in adolescents and adults who have either osteosarcoma or soft tissue sarcoma. The primary endpoints are PFS and confirmed ORR; secondary endpoints include safety, DOR and patient-reported outcome measures.

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 enquiries

Media:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Sarah Clements	+44 (0) 20 8047 5502	(London)
	Madison Goring	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Alison Hunt	+1 540 742 3391	(Washington DC)

Investor Relations:	James Dodwell	+44 (0) 7881 269066	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Joanna Tuplin	+44 (0) 7788 351650	(London)
	Sam Piper	+44 (0) 7824 525779	(London)
	Dan Smith	+44 (0) 7823 523885	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 3126	(Philadelphia)

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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No. 3888792

Registered Office:

79 New Oxford Street
London
WC1A 1DG

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