Stock-exchange announcement

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GSK's licensor Hansoh Pharma announces positive results from a second phase III trial for Ris-Rez in China

- ARTEMIS-011, a phase III study conducted for China, met its primary endpoint of progression-free survival in relapsed osteosarcoma
- Results add to a growing body of positive late-stage evidence for Ris-Rez, including recent pivotal data in advanced or relapsed small-cell lung cancer
- GSK is advancing development of Ris-Rez 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-011, its pivotal phase III trial evaluating risvutatug rezetecan (Ris-Rez) in patients with osteosarcoma who have progressed or relapsed after receiving at least two prior lines of systemic therapy, met its primary endpoint of progression-free survival (PFS).

In the trial, conducted in patients in China, Ris-Rez, a B7-H3-targeted antibody-drug conjugate (ADC), demonstrated statistically significant and clinically meaningful improvements in PFS compared with chemotherapy. Consistent benefit was also observed across secondary endpoints, including overall survival. The safety profile of ARTEMIS-011 is consistent with prior findings in this tumour type, and no new safety signals were identified. These data will be used by Hansoh Pharma for regulatory submission in China.

GSK is advancing EMBOLD Sarcoma-202, a global phase Ib/II trial of Ris-Rez in previously treated unresectable advanced or metastatic sarcomas, including osteosarcoma. The study is part of GSK's broader clinical development programme across multiple solid tumours, including lung and prostate cancers, under its exclusive global rights to develop Ris-Rez outside mainland China, Hong Kong, Macau and Taiwan. Ris-Rez has US FDA Breakthrough Therapy Designation in relapsed or refractory osteosarcoma.

Today's results from Hansoh follow recently reported pivotal data in advanced or relapsed small-cell lung cancer (SCLC), making Ris-Rez the only B7-H3-targeted ADC to deliver positive phase III outcomes across multiple tumour types.

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK said: "Building on recent pivotal data in small-cell lung cancer, these results strengthen our confidence in the broad potential of Ris-Rez and validate B7-H3 as a promising target across multiple tumour types."

Osteosarcoma mainly affects children and young adults and is the most common primary bone cancer, accounting for 20-40% of all bone cancers[1]. It is a rare bone cancer with a global incidence of approximately 3.4 cases per million people per year[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 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 extensive-stage SCLC (ES-SCLC); and Breakthrough Therapy 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 women's cancers into lung and gastrointestinal cancers, as well as other solid tumours. This includes accelerating priority programmes such as antibody-drug conjugates Ris Rez targeting B7-H3 and Mo-Rez targeting B7-H4, and velzatinib, 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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