Press release

For media and investors only

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GSK’227, a B7-H3-targeted antibody-drug conjugate, granted Orphan Drug Designation in small-cell lung cancer by the US FDA

- Designation supported by early clinical data showing durable responses in certain types of small-cell lung cancer (SCLC)
- Extensive stage SCLC is associated with high rates of relapse, few treatment options and poor prognosis
- Fifth regulatory designation further supports plan to accelerate development of GSK’227 in solid tumours with transformational potential

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GSK plc (LSE/NYSE: GSK) today announced that its B7-H3-targeted antibody-drug conjugate GSK’227, now referred to by its International Nonproprietary Name, risvutatug rezetecan, has received Orphan Drug Designation (ODD) from the US Food and Drug Administration (FDA) for the treatment of small-cell lung cancer (SCLC). The ODD was supported by preliminary clinical data showing durable responses in patients with extensive stage SCLC (ES-SCLC) who were treated with risvutatug rezetecan in the phase I ARTEMIS-001 clinical trial.[1]

In the US, SCLC constitutes about 13% of all lung cancers. In 2025, an estimated 29,500 people in the US will be diagnosed with SCLC.[2] Of patients with SCLC, 70% have extensive-stage disease, meaning the cancer has spread throughout one or both lungs and/or to other parts of the body.[3] ES-SCLC is an aggressive and difficult-to-treat cancer with limited treatment options. The 5-year survival rate is approximately 3%.[3] Most patients with ES-SCLC relapse after initial treatment and the median overall survival with standard-of-care treatments for relapsed ES-SCLC is approximately 8 months.[4]

This designation follows the recent announcement that risvutatug rezetecan was granted ODD from the European Medicines Agency (EMA) for the treatment of pulmonary neuroendocrine carcinoma, a category of cancer that includes SCLC. It is the fifth regulatory designation for risvutatug rezetecan, exemplifying the potential of this B7-H3-targeted ADC, which is being developed in a range of solid tumours, including lung, prostate and colorectal cancers. Previously, risvutatug rezetecan was granted Priority Medicines (PRIME) Designation by the EMA for relapsed or refractory ES-SCLC and Breakthrough Therapy Designations for relapsed or refractory ES-SCLC and relapsed or refractory osteosarcoma granted by the US FDA.[5,6,7]

About risvutatug rezetecan

Risvutatug rezetecan (GSK5764227) is a novel investigational B7-H3-targeted antibody-drug conjugate 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 risvutatug rezetecan. GSK’s global phase III trial (NCT07099898) for risvutatug rezetecan in relapsed ES-SCLC began in August 2025.

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 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 2024, and GSK's Q3 Results for 2025.

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[1] Wang J, et al. Presented at IASLC WCLC 2024.
[2] Cancer Facts and Figures 2025, American Cancer Society, accessed 6 November 2025
[3] SEER Explorer Surveillance Research Program, National Cancer Institute, accessed 27 October 2025.
[4] G. Mountzios, et al. Tarlatamab in small-cell lung cancer after platinum-based chemotherapy. N Engl J Med, 393 (2025), pp. 349-361. DOI: 10.1056/NEJMoa2502099
[5] GSK. GSK receives US FDA Breakthrough Therapy Designation for its B7-H3-targeted antibody-drug conjugate in relapsed or refractory extensive-stage small-cell lung cancer. Available at: https://www.gsk.com/en-gb/media/press-releases/gsk-receives-us-fda-breakthrough-therapy-designation/.
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[7] GSK. GSK's B7-H3-targeted antibody-drug conjugate, GSK'227, receives US FDA Breakthrough Therapy Designation in late-line relapsed or refractory osteosarcoma. Available at: https://www.gsk.com/en-gb/media/press-releases/gsk-b7-h3-targeted-antibody-drug-conjugate-gsk227-receives-us-fda-breakthrough-therapy-designation-in-late-line-relapsed-or-refractory-osteosarcoma/.