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## **GSK's B7-H3-targeted antibody-drug conjugate, risvutatug rezetecan, granted Orphan Drug Designation for small-cell lung cancer in Japan**

- 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
- Sixth global regulatory designation for risvutatug rezetecan supporting GSK's investigational ADC with transformational potential in solid tumours

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GSK plc (LSE/NYSE: GSK) today announced that risvutatug rezetecan (or Ris-Rez, for short), a B7-H3-targeted antibody-drug conjugate (ADC), has received Orphan Drug Designation (ODD) from Japan's Ministry of Health, Labour and Welfare 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 Ris-Rez in the phase I ARTEMIS-001 clinical trial.<sup>1</sup> This is the sixth regulatory designation for Ris-Rez, which is being developed in a range of solid tumours, including lung, prostate and colorectal cancers.

Lung cancer is the second most common cancer in Japan, and SCLC makes up 10-15% of cases.<sup>2,3</sup> Of patients with SCLC, 70% have ES-SCLC, meaning the cancer has spread throughout one or both lungs and/or to other parts of the body.<sup>4</sup> ES-SCLC is an aggressive and difficult-to-treat cancer with limited treatment options and poor long-term survival. Most patients with ES-SCLC relapse after initial treatment and the median overall survival with standard-of-care for these patients is approximately 8 months.<sup>5</sup>

### **About Ris-Rez**

Ris-Rez 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 Ris-Rez. GSK's global phase III trial (NCT07099898) for Ris-Rez in relapsed ES-SCLC began in August 2025.

Regulatory designations received for Ris-Rez to date include ODDs from the US Food and Drug Administration (FDA) 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 Designations for relapsed or refractory ES-SCLC and relapsed or refractory osteosarcoma from the US FDA.<sup>6,7,8</sup>

### **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](http://www.gsk.com).

### **GSK enquiries**

# Press release

## For media and investors only



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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.

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<sup>1</sup> Wang J, et al. Presented at IASLC WCLC 2024.

<sup>2</sup> GLOBOCAN 2022 <https://gco.iarc.who.int/media/globocan/factsheets/populations/392-japan-fact-sheet.pdf> Accessed 9 March 2026

<sup>3</sup> Japan Lung Cancer Society. Lung Cancer Clinical Practice Guidelines 2025 Edition. Available at <https://www.haigan.gr.jp/publication/guideline/examination/2025/>

<sup>4</sup> SEER Explorer Surveillance Research Program, National Cancer Institute, accessed 27 October 2025.

<sup>5</sup> 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

<sup>6</sup> 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/>.

<sup>7</sup> GSK. GSK's B7-H3-targeted antibody-drug conjugate, GSK'227, receives EMA Priority Medicines (PRIME) Designation in relapsed extensive-stage small-cell lung cancer. Available at: <https://www.gsk.com/en-gb/media/press-releases/b7-h3-targeted-antibody-drug-conjugate-receives-ema-priority-medicines-designation-in-relapsed-extensive-stage-small-cell-lung-cancer/>.

<sup>8</sup> 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/>.