Press release
For media and investors only

Issued: 28 October 2025, London UK

GSK's B7-H3-targeted antibody-drug conjugate, GSK'227, receives Orphan Drug Designation in the EU

- Regulatory designation based on encouraging early clinical data showing potential for GSK'227 in small-cell lung cancer
- Patients with relapsed or refractory extensive stage small-cell lung cancer often face a debilitating quality of life, limited therapies and poor outcomes
- Fourth designation further supports GSK plans to accelerate ADC development in a range of solid tumours with transformational potential

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GSK plc (LSE/NYSE: GSK) today announced that GSK5764227 (GSK'227), its B7-H3-targeted antibody-drug conjugate (ADC), has received Orphan Drug Designation (ODD) from the European Medicines Agency (EMA) for the treatment of pulmonary neuroendocrine carcinoma (NEC), a category of cancer that includes 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 GSK'227 in the phase I ARTEMIS-001 clinical trial.[i]

This ODD recognises the potential of GSK'227 to address a significant unmet need for ES-SCLC, an aggressive type of NEC with poor outcomes and limited treatment options. An estimated 250,000 patients globally are diagnosed with SCLC each year and it is responsible for approximately 200,000 deaths annually.[ii]

This is the fourth regulatory designation for GSK'227, exemplifying the potential of this targeted ADC, which is being developed in a range of solid tumour types, including in lung, prostate and colorectal cancers. Previously, GSK'227 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.[iii,iv,v]

About GSK'227
GSK'227 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 GSK'227. GSK's global phase III trial for GSK'227 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 Q2 Results for 2025.

Registered in England & Wales:
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[i] Wang J, et al. Presented at IASLC WCLC 2024
[ii] Qian Wang, Zeynep H. Gümüş, Cristina Colarossi, Lorenzo Memeo, Xintong Wang, Chung Yin Kong, Paolo Boffetta, SCLC: Epidemiology, Risk Factors, Genetic Susceptibility, Molecular Pathology, Screening, and Early Detection, Journal of Thoracic Oncology, Volume 18, Issue 1, 2023, Pages 31-46, ISSN 1556-0864, https://doi.org/10.1016/j.jtho.2022.10.002.
[iii] 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/.
[iv] 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/.
[v] 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/.