Press release

For media and investors only

Issued: 16 December 2024, London UK

GSK's B7-H3-targeted antibody-drug conjugate, GSK'227, receives EMA Priority Medicines (PRIME) Designation in relapsed extensive-stage small-cell lung cancer

- Regulatory designation based on promising preliminary clinical data
- PRIME Designation granted to medicines with potential to address significant unmet medical needs
- Extensive-stage small-cell lung cancer is associated with high rates of relapse, few treatment options and poor prognosis

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GSK plc (LSE/NYSE: GSK) announced today that the European Medicines Agency (EMA) has granted Priority Medicines (PRIME) Designation for GSK5764227 (GSK'227), its B7-H3-targeted antibody-drug conjugate (ADC) being evaluated for the treatment of patients with relapsed extensive-stage small-cell lung cancer (ES-SCLC). The PRIME Designation supports the development of medicines with potential to offer a major therapeutic advantage for patients.[1] This is the second regulatory designation for GSK'227, following the US Food and Drug Administration's decision to grant Breakthrough Therapy Designation in August 2024[2].

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: "This PRIME Designation is an important step forward as we seek to accelerate development of GSK'227 in extensive-stage small-cell lung cancer and other tumour types with limited treatments. Our investigational B7-H3-targeted ADC is a key component of our broader ADC programme."

The EMA's PRIME Designation is supported by preliminary clinical data from the ARTEMIS-001 study. This is an ongoing phase I open-label, multi-centre trial of more than 200 patients evaluating the safety, tolerability, and preliminary anti-tumour activity in locally advanced or metastatic solid tumours, including relapsed ES-SCLC, conducted by Hansoh Pharma. The efficacy and safety results from this trial were presented at the 2024 World Conference on Lung Cancer earlier this year. GSK recently began a global phase I trial to support a registrational pathway for GSK'227.

Lung cancer is a leading cause of cancer-related morbidity and mortality worldwide.[3] In Europe, there were an estimated 484,554 new cases and 375,784 deaths from lung cancer in 2022.[4] SCLC represents 10-15% of all lung cancer cases and is among the deadliest subtypes.[5,6] ES-SCLC constitutes 60% to 85% of all SCLC cases at diagnosis and is characterised by tumours that have spread beyond the lungs.[7] Platinum resistant or refractory patients typically have very poor outcomes, with median overall survival of less than six months.[8, 9]

Earlier this year, GSK acquired exclusive worldwide rights (excluding China's mainland, Hong Kong, Macau, and Taiwan) from Hansoh to progress clinical development and commercialisation of GSK'227.[10]

About GSK'227

GSK'227, also known as HS-20093, is a novel investigational B7-H3-targeted ADC composed of a fully human anti-B7-H3 monoclonal antibody covalently linked to a topoisomerase inhibitor (TOPOi) payload. HS-20093 is being developed by Hansoh Pharma for the treatment of lung cancer, sarcoma, head and neck cancers and other solid tumours in multiple phase I, II and III clinical trials in China. GSK's global phase I trial for GSK'227 began in August 2024.

GSK in oncology
Oncology is an emerging therapeutic area for GSK where we are committed to maximising patient survival with a current focus on haematologic malignancies, gynaecologic cancers, and other solid tumours through breakthroughs in immuno-oncology and tumour-cell targeting therapies.

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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