Press release

For media and investors only

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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

- Regulatory designation based on promising early clinical evidence observed with GSK5764227 in this tumour type
- Breakthrough Therapy Designation aims to expedite development and review of drugs with potential to show improvement over available therapies for serious conditions
- Patients with this aggressive form of lung cancer who experience disease progression on or after chemotherapy have limited treatment options that typically result in poor outcomes

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GSK plc (LSE/NYSE: GSK) announced today that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for GSK5764227 (GSK'227), the Company's investigational B7-H3-targeted antibody drug conjugate (ADC) being evaluated for the treatment of patients with extensive-stage small-cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy (relapsed or refractory). The Breakthrough Therapy Designation aims to expedite the development and review of drugs with the potential to treat a serious condition and where preliminary clinical evidence may indicate substantial improvement over currently available therapy.[1]

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: "Extensive-stage small-cell lung cancer is aggressive with poor prognosis and significant need for new treatments. Today's Breakthrough Therapy Designation supports our ambition to accelerate GSK'227 for these patients as part of our broader ADC programme focused on developing new treatment options with transformational and first-to-market potential."

Lung cancer is one of the most common cancers worldwide. In the US, approximately 15% of all lung cancers are small-cell. Of patients with small-cell lung cancer, 70% have extensive-stage disease meaning the cancer has spread throughout one or both lungs and/or to other parts of the body[2]. ES-SCLC is an aggressive and difficult-to-treat cancer with limited treatment options. The 5-year survival rate is approximately 3%[2]. Most patients with ES-SCLC relapse after initial treatment and the median overall survival with current standard-of-care treatments for relapsed ES-SCLC is 5-6 months[3] [4].

Earlier this year, 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[5]. FDA's Breakthrough Therapy Designation is supported by data from the ongoing ARTEMIS-001 Phase 1 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 or refractory ES-SCLC, conducted by Hansoh Pharma. Results from this trial will be presented at the 2024 World Conference on Lung Cancer taking place from 7-10 September in San Diego, California, USA. GSK plans to begin global phase 1/2 trials in 2H 2024 to support a registrational pathway for GSK'227.

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About GSK5764227

GSK5764227, also known as HS-20093, is a novel investigational B7-H3-targeted antibody-drug conjugate composed of a fully humanised anti-B7-H3 monoclonal antibody covalently linked to 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 and II clinical trials in China, with GSK's global Phase I trials for GSK5764227 set to begin in 2H 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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[5] https://www.gsk.com/en-gb/media/press-releases/gsk-enters-exclusive-license-agreement-with-hansoh-for-hs-20093/