Press release

For media and investors only

Issued: 7 January 2025, London UK

GSK's B7-H3-targeted antibody-drug conjugate, GSK'227, receives US FDA Breakthrough Therapy Designation in late-line relapsed or refractory osteosarcoma

- Regulatory designation based on promising early data in this rare bone cancer
- Breakthrough Therapy Designation granted to drugs with potential to show improvement for serious conditions
- There are no FDA-approved treatments for patients with osteosarcoma who have progressed on two prior lines of therapy

GSK plc (LSE/NYSE: GSK) announced today that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for GSK5764227 (GSK'227), its B7-H3-targeted antibody-drug conjugate (ADC) being evaluated for the treatment of adult patients with relapsed or refractory osteosarcoma (bone cancer) who have progressed on at least two prior lines of therapy. 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] This is the third regulatory designation for GSK'227, following the European Medicines Agency's decision to grant Priority Medicines (PRIME) designation and the FDA's decision to grant Breakthrough Therapy Designation for relapsed or refractory extensive-stage small-cell lung cancer in August 2024 and December 2024, respectively.[2,3]

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: "This latest regulatory designation for GSK'227 exemplifies the potential of our targeted ADC in patients with difficult to treat cancers. For patients with relapsed or refractory osteosarcoma, there is an urgent unmet medical need with no approved treatment options once the cancer returns a second time, and chemotherapy provides limited benefit in this setting."

The US FDA's Breakthrough Therapy Designation is supported by data from the ARTEMIS-002 study. This is a phase II, open-label, randomised, multi-centre, clinical trial evaluating the efficacy and safety of GSK'227 in patients with relapsed or refractory osteosarcoma and other unresectable bone and soft tissue sarcomas, conducted by Hansoh Pharma. More than 60 patients were enrolled, including 42 patients with osteosarcoma. Results from ARTEMIS-002 were presented at the 2024 American Society of Clinical Oncology Annual Meeting.[4] Last 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. GSK recently began a global phase I trial (NCT06551142) as a part of the development plan to support a registrational pathway for GSK'227.

Osteosarcoma mainly affects children and young adults and is the most common primary bone cancer, accounting for 20-40% of all bone cancers.[5] It is a rare disease with an annual incidence of 3.3 patients per million in the US, representing less than 1% of all new cancer diagnoses.[6,7] Approximately 20-30% of patients who present with localised (non-metastatic) osteosarcoma and 80% of those who present with metastatic osteosarcoma experience relapsed or refractory disease.[8] Following first-line chemotherapy, treatment options for patients with relapsed or refractory osteosarcoma are severely limited, with no clear standard of care available.[9] After patients progress on two prior lines of treatment, options become even more limited, with no approved therapies.

About GSK'227

GSK'227, also known as HS-20093, 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. 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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