Stock-exchange announcement
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Velzatinib granted Orphan Drug Designation (ODD) in Japan in GIST

- Designation supported by StrateGIST 1 data showing promising anti-tumour activity and tolerability profile
- Adds to US FDA Fast Track Designation and ODDs in the US and EU
- Phase III studies accelerated in first- and second-line GIST

GSK plc (LSE/NYSE: GSK) today announced that velzatinib, a novel, highly selective KIT inhibitor, has received Orphan Drug Designation (ODD) from Japan's Ministry of Health Labour and Welfare for the treatment of gastrointestinal stromal tumour (GIST). The ODD was supported by data from the ongoing phase I/Ib StrateGIST 1 trial in advanced GIST, which showed promising anti-tumour activity and a promising tolerability profile.[1] In addition to the ODD in Japan, velzatinib has been granted US Food and Drug Administration (FDA) Fast Track designation, and US and European Union (EU) ODD.

GSK is accelerating the development of velzatinib, with phase III trials under way in first- and second-line advanced / metastatic GIST.[2,3] Enrolment in the second-line clinical trial is tracking ahead of schedule, reflecting strong interest in velzatinib from the GIST community, with data expected in the second half of 2027.

Additional data for velzatinib will be shared at the Connective Tissue Oncology Society (CTOS) Annual Meeting 2026 (18-21 November, Seoul, South Korea). Seven abstracts will be presented, including clinical analyses of velzatinib in first- and second-line GIST by *KIT* mutation, preclinical research on mutation coverage and work on translational biomarkers. These data will further support velzatinib's development across different *KIT* mutations and lines of therapy, where resistance and tolerability remain significant challenges.

About velzatinib

Velzatinib is a novel, highly selective KIT inhibitor specifically designed for gastrointestinal stromal tumour (GIST). This monotherapy targets all clinically relevant primary and key secondary *KIT* mutations, addressing a major unmet need in GIST treatment where tolerability is challenging and resistance arises from diverse *KIT* mutations.

About GIST

Gastrointestinal stromal tumour (GIST) is a rare type of cancer most commonly arising in the stomach and small intestine. Globally, approximately 80,000 to 120,000 patients are diagnosed with GIST annually.[4] 80% of GIST cases are driven by mutations in the *KIT* gene that lead to the growth, proliferation and survival of tumour cells (primary or activating mutations in exons 9 and 11).[5] Additionally, about 90% of patients treated in the 1st-line develop new *KIT* mutations (secondary or resistance mutations in exons 13 and 17) that typically lead to relapse with limited therapeutic options.[6] There are no approved tyrosine kinase inhibitors (TKIs) that inhibit the full spectrum of clinically relevant primary and secondary mutations in *KIT*.

In Japan, the age-adjusted annual incidence of GIST is one of the highest in the world, at approximately 4 per 100,000 people.[7] While outcomes for people with GIST have improved over the past two decades, the five-year survival rate remains significantly lower once the disease has spread.[8] An additional phase II trial with velzatinib – StrateGIST J – is underway in Japan, evaluating patients whose disease has progressed, or who are intolerant to available treatment options.[9]

GSK in oncology
GSK is focused on developing differentiated medicines for cancers where patients continue to face poor outcomes, treatment resistance, limited options or significant treatment burden. We focus where advances in science and technology offer the greatest opportunity to improve outcomes across haematological, lung, gastrointestinal, genitourinary and gynaecological cancers. Across multiple modalities, including targeted small molecules, antibody-drug conjugates (ADCs) and immunotherapies, GSK applies deep expertise in cancer biology and immune system science to develop differentiated medicines designed to deliver durable responses, overcome resistance and reduce treatment burden.

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.

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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, and GSK's Q3 Results for 2026.

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