Stock-exchange announcement
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Jemperli (dostarlimab) achieves sustained clinical complete responses in dMMR/MSI-H locally advanced rectal cancer

- Primary objective met in interim analysis, with clinically significant rate of participants showing no detectable signs of cancer one year or more after treatment
- Results support potential for dostarlimab to eliminate the need for chemotherapy, radiation and surgery in some patients
- Data to be shared with health authorities for regulatory review, including accelerated review in the US

GSK plc (LSE/NYSE: GSK) today announced positive interim results from the registrational phase II AZUR-1 trial of *Jemperli* (dostarlimab) in patients with stage II/III mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) locally advanced rectal cancer. The single arm trial met its primary objective, showing a meaningful and sustained clinical complete response rate at 12 months (cCR12).

These results support the potential for dostarlimab, if approved, to become the first immunotherapy capable of eliminating or delaying the need for chemotherapy, radiation and surgery for some patients in this population.

Rectal cancer, a type of bowel cancer, affects around 730,000 people globally each year[1] and approximately 5-10% of all rectal cancers have the dMMR/MSI-H subtype[2]. Current standard of care typically includes chemotherapy, radiation, and surgery[3]. While often effective, these treatments can profoundly impact a patient's quality of life, potentially leading to lifelong use of a colostomy bag, significant physiological dysfunction, and infertility[4,5,6].

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: "The AZUR-1 results support the potential for dostarlimab to transform treatment for dMMR/MSI-H locally advanced rectal cancer. For many patients today, rectal cancer treatment comes with the tolerability burden and lasting impacts from chemotherapy, radiation and surgery. These data demonstrate that some patients may be able to avoid those interventions while remaining free of detectable signs of cancer."

AZUR-1 results represent a substantial improvement compared to the historical standard of care[7] and build on earlier research conducted in collaboration with Memorial Sloan Kettering Cancer Center, which first demonstrated the potential for dostarlimab to achieve clinical complete responses without other treatments in patients with dMMR/MSI-H locally advanced rectal cancer.

In interim data, the safety and tolerability profile of dostarlimab was consistent with its well-characterised and manageable safety profile observed across solid tumours.

Dostarlimab has received both Breakthrough Therapy and Fast Track designations from the US Food and Drug Administration (FDA) in this setting. GSK plans to share interim AZUR-1 data with global regulatory authorities to support review. Detailed results will be presented at a future scientific congress.

About stage II/III dMMR/MSI-H locally advanced rectal cancer
Around 5–10% of rectal cancers are mismatch repair-deficient (dMMR) or microsatellite instability-high (MSI-H)[8]. These tumours have a specific genetic characteristic where they are unable to properly repair DNA damage, leading to an accumulation of mutations. This unique biological feature often makes them highly responsive to immunotherapies like dostarlimab[9,10]. These biomarkers are most commonly found in colorectal, endometrial and other gastrointestinal cancers, but can also be present in other solid tumours[11].

About AZUR-1
AZUR-1 is a global, open-label, single-arm, registrational phase II trial evaluating dostarlimab monotherapy in patients with stage II/III dMMR/MSI-H locally advanced rectal cancer. The trial was designed to assess sustained clinical complete responses for 12 months (cCR12) and determine whether dostarlimab alone could enable patients to avoid chemotherapy, radiation and/or surgery. A total of 154 participants received nine cycles of dostarlimab over six months, administered as a 500 mg intravenous infusion every three weeks.

About *Jemperli* (dostarlimab)
Jemperli, a programmed death receptor-1 (PD-1)-blocking antibody, is the backbone of GSK's ongoing immuno-oncology-based research and development programme. A robust clinical trial programme includes studies of *Jemperli* alone and in combination with other therapies in gynaecologic, colorectal and head and neck cancers, as well as where there are opportunities for transformational outcomes.

Jemperli was discovered by AnaptysBio, Inc. and licensed to TESARO, Inc., under a collaboration and exclusive license agreement signed in March 2014. Under this agreement, GSK is responsible for the ongoing research, development, commercialisation, and manufacturing of *Jemperli.*

More information about *Jemperli*, its indications and complete important safety information is available at EU product information[12] and US product information[13]. *Jemperli* is not currently approved anywhere in the world for rectal cancer.

GSK in oncology
Our ambition in oncology is to help increase overall quality of life, maximise survival and change the course of disease, expanding from our current focus on blood and gynaecologic cancers into lung and gastrointestinal cancers, as well as other solid tumours. This includes accelerating priority programmes such as antibody-drug conjugates targeting B7-H3 and B7-H4, and velzatinib, a highly selective KIT tyrosine kinase inhibitor.

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 Q1 Results for 2026.

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