Stock-exchange announcement
For media and investors only

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Jemperli (dostarlimab) accepted for priority review by the US FDA for dMMR/MSI-H locally advanced rectal cancer

- Submission supported by AZUR-1 data showing significant proportion of participants with no detectable signs of cancer one year or more after treatment
- If approved, *Jemperli* could eliminate the need for chemotherapy, radiation, and surgery for some patients
- Application accepted under Project Orbis, an initiative to potentially expedite approvals through coordinated international regulatory reviews

GSK plc (LSE/NYSE: GSK) today announced the US Food and Drug Administration (FDA) has accepted for priority review a supplemental Biologics License Application (sBLA) for *Jemperli* (dostarlimab) for patients with previously untreated stage II and III mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) locally advanced rectal cancer. The FDA has assigned a PDUFA action date of February 2027. The application is also eligible for expedited review through the National Priority Voucher program, which could result in an earlier FDA decision[1].

Rectal cancer, a type of bowel cancer, affects around 770,000 people globally each year[2] and approximately 5-10% of cases have the dMMR/MSI-H subtype[3]. Chemotherapy, radiation and surgery are the standard of care and while often effective, they can have lasting adverse effects on bowel, urinary and sexual function, fertility and overall quality of life[4,5,6].

The application is based on positive data from the registrational phase II, single-arm AZUR-1 trial, which met its primary objective by demonstrating a meaningful and sustained clinical complete response rate for 12 months (cCR12) with no detectable signs of cancer for at least one year. In interim data, the safety and tolerability profile of dostarlimab was generally consistent with its well-characterised and manageable safety profile observed across solid tumours. These data will be submitted for presentation at a scientific congress later in 2026.

AZUR-1 results represent a substantial improvement compared to the historical standard of care[7]. The data 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. These findings build on earlier research conducted with Memorial Sloan Kettering Cancer Center (MSK), 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.

Dostarlimab was previously granted Fast Track and Breakthrough Therapy Designations in this setting[8,9]. The application has also been accepted under Project Orbis, an FDA Oncology Center of Excellence initiative that enables coordinated reviews by international health authorities and may support earlier regulatory decisions and patient access. Regulatory decisions remain independent in each country.

About stage II and III dMMR/MSI-H locally advanced rectal cancer
Rectal cancer affects around 770,000 people globally each year[2]. Around 5–10% of rectal cancers are mismatch repair-deficient (dMMR) or microsatellite instability-high (MSI-H)[3]. 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[10,11]. These biomarkers are most commonly found in endometrial, colorectal and other gastrointestinal cancers, but can also be present in other solid tumours[12].

About AZUR-1
AZUR-1 is a global, open-label, single-arm, registrational phase II trial evaluating dostarlimab monotherapy in patients (n=154) with previously untreated stage II and 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 surgery. Patients received nine cycles of dostarlimab over six months, administered as a 500mg intravenous infusion every three weeks. In interim data, the safety and tolerability profile of dostarlimab was generally consistent with its well-characterised and manageable safety profile observed across solid tumours.

The AZUR-1 results represent a substantial improvement compared to the historical standard of care. They 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.

About *Jemperli*
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 the product and its indications is available at EU product information[13] and US product information[14]. *Jemperli* is not currently approved anywhere in the world for locally advanced 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 women's cancers into lung and gastrointestinal cancers, as well as other solid tumours. This includes accelerating priority programmes such as antibody-drug conjugates Ris-Rez targeting B7-H3 and Mo-Rez targeting 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 Q2 Results for 2026.

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References

1. FDA press release issued 6 November, 2025. FDA Awards Second Batch of National Priority Vouchers. Available at https://www.fda.gov/news-events/press-announcements/fda-awards-second-batch-national-priority-vouchers
2. International Agency for Research on Cancer (IARC) (2024) Rectum cancer fact sheet: GLOBOCAN 2022. World Health Organization. Available at: https://gco.iarc.who.int/media/globocan/factsheets/cancers/9-rectum-fact-sheet.pdf. Accessed August 2026
3. Cercek A, et al. Mismatch Repair-Deficient Rectal Cancer and Resistance to Neoadjuvant Chemotherapy. Clin Cancer Res. 2020 Jul 1;26(13):3271-3279. doi: 1158/1078-0432.CCR-19-3728. Epub 2020 Mar 6. PMID: 32144135; PMCID: PMC7348681
4. Cercek, A., Lumish, M., Sinopoli, J. et al. (2022) 'PD-1 blockade in mismatch repair–deficient, locally advanced rectal cancer', New England Journal of Medicine, 386(25), pp. 2363–2376. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa2201445
5. Negro, S. et al. (2025) 'Quality of life in rectal cancer treatments: a systematic review', Cancers, 17(14), 2310. Available at: https://www.mdpi.com/2072-6694/17/14/2310
6. Neibart, S.S. *et al.* (2020) 'Quality of life after radiotherapy for rectal cancer', *Current Colorectal Cancer Reports*, 16(1), pp. 1–10. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC7336840/
7. Cercek A, Roxburgh CS, Strombom P, et al. Adoption of Total Neoadjuvant Therapy for Locally Advanced Rectal Cancer. JAMA Oncol. 2018;4(6):e180071. doi:10.1001/jamaoncol.2018.0071
8. GSK press release issued 16 December 2024. Jemperli (dostarlimab) receives US FDA Breakthrough Therapy Designation for locally advanced dMMR/MSI-H rectal cancer. Available at https://www.gsk.com/en-gb/media/press-releases/jemperli-dostarlimab-receives-us-fda-breakthrough-therapy-designation-for-locally-advanced-dmmrmsi-h-rectal-cancer/
9. GSK press release issued 9 February 2023. US FDA Advisory Committee votes in support of trials designed to evaluate Jemperli (dostarlimab-gxly) as a potential treatment for mismatch repair-deficient/microsatellite instability-high locally advanced rectal cancer. Available at https://www.gsk.com/en-gb/media/press-releases/us-fda-advisory-committee-votes-in-support-of-trials-designed-to-evaluate-jemperli-dostarlimab-gxly-as-a-potential-treatment-for-dmmrmsi-h-locally-advanced-rectal-cancer/
10. Andre T, Berton D, Curigliano G, et al. Antitumor Activity and Safety of Dostarlimab Monotherapy in Patients With Mismatch Repair Deficient Solid Tumors: A Nonrandomized Controlled Trial. JAMA Netw Open. 2023;6(11):e2341165. doi:10.1001/jamanetworkopen.2023.41165.
11. Le DT, et al. PD-1 blockade in tumors with mismatch repair deficiency. N Engl J Med. 2015;372(26):2509-2520.
12. National Cancer Institute at the National Institutes of Health. Definition of mismatch repair deficiency. Accessed August 2026. Available at: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mismatch-repair-deficiency
13. JEMPERLI (dostarlimab) Summary of Product Characteristics. GlaxoSmithKline (Ireland) Limited. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/jemperli. Accessed August 2026.
14. JEMPERLI (dostarlimab-gxly) prescribing information. GlaxoSmithKline. Available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Jemperli/pdf/JEMPERLI-PI-MG.PDF/. Accessed August 2026.