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For media and investors only



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***Jemperli* (dostarlimab) approved in US as first and only immunotherapy for adults with MSI-H/dMMR locally advanced rectal cancer**

- Approval based on AZUR-1 data showing clinically significant proportion of participants with no detectable signs of cancer one year or more after treatment
- No disease recurrences reported among responders after median follow up of more than two years
- *Jemperli* monotherapy could help eligible patients avoid chemotherapy, radiation and surgery

GSK plc (LSE/NYSE: GSK) today announced the US Food and Drug Administration (FDA) has approved *Jemperli* (dostarlimab) as the first and only immunotherapy for adults with stage II and III microsatellite instability-high (MSI-H)/mismatch repair deficient (dMMR) locally advanced rectal cancer under the accelerated approval pathway.

Current standard of treatment for locally advanced rectal cancer includes chemotherapy, radiation and surgery¹, but these can have lasting consequences, including bowel, urinary and sexual dysfunction, secondary cancers and infertility^{2,3}. For patients with MSI-H/dMMR tumours, a biomarker found in around 5-10% of rectal cancers⁴, *Jemperli* monotherapy could help avoid these interventions.

Tony Wood, Chief Scientific Officer, GSK, said: “Today, *Jemperli* becomes the first and only approved immunotherapy for adults in the US with MSI-H/dMMR locally advanced rectal cancer. For decades, treatment has relied on chemotherapy, radiation and surgery. This approval offers a new treatment approach and represents an important step towards more personalised care for these patients.”

Dr Andrea Cercek, MD, Principal Investigator of AZUR-1, Section Head of Colorectal Cancer and Co-Director of the Center for Young Onset Colorectal and Gastrointestinal Cancer, Memorial Sloan Kettering Cancer Center, said: “The AZUR-1 results demonstrate the potential for a fundamentally different treatment approach in this biomarker-defined patient population, and today’s approval means MSI-H/dMMR patients can now access a licensed treatment tailored to the biology of their disease.”

Michael Sapienza, CEO, Colorectal Cancer Alliance, said: “People facing rectal cancer are often thinking not only about treating their disease, but also worrying about what life will look like afterwards. The possibility of avoiding chemotherapy, radiation and surgery represents a meaningful advance for patients and their families. Biomarker testing at diagnosis will be essential to identifying patients who may be eligible for this treatment and helping them understand their options.”

Approval was based on data from the phase II AZUR-1 trial. The study met its primary objective, demonstrating a clinically significant proportion of participants achieved sustained clinical complete responses at 12 months (cCR12), with data continuing to mature.

Investigator-assessed data, a clinically relevant endpoint, showed 68% of evaluable patients (98/144; 95% CI: 60%, 76%) achieved cCR12. In an exploratory analysis, 76% (110/144; 95% CI: 69%, 83%) of evaluable patients had no evidence of cancer one year or more after treatment. This includes 68% (98/144) (95% CI: 60%, 76%) of patients who reached cCR12 without surgery, plus other participants (n=12) who had their complete response confirmed through tissue analysis after surgery (pathological complete response, or pCR). No disease recurrences have been reported among responders to date, after a median follow up of more than two years.

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Data on the primary objective, cCR12 assessed by independent central review, continue to mature. 47% (54/116) (95% CI: 37%, 56%) of evaluable patients have achieved cCR12. An additional 38 participants who are still progressing through to 12 month follow up have already achieved a clinical complete response.

The safety profile of *Jemperli* was generally consistent with its established profile across solid tumours. Serious adverse reactions occurred in 20% of patients receiving *Jemperli*, and the most common adverse reactions were fatigue (32%), rash (22%), diarrhoea (18%) and pruritus (17%). *Jemperli* was permanently discontinued due to adverse reactions in 3% of patients.

Full data from the AZUR-1 interim analysis will be presented at the European Society for Medical Oncology (ESMO) Congress in October 2026.

Jemperli has received FDA Fast Track and Breakthrough Therapy designations for this indication. The application was also granted Priority Review and received a National Priority Voucher, resulting in an accelerated approval ahead of the PDUFA date.

The supplemental Biologics License Application (sBLA) is being reviewed under Project Orbis, an FDA Oncology Center of Excellence initiative that enables concurrent review by international health authorities. Regulatory reviews are ongoing in participating countries.

About stage II/III MSI-H/dMMR locally advanced rectal cancer

Around 5–10% of rectal cancers are microsatellite instability-high (MSI-H) or mismatch repair-deficient (dMMR)⁴. 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^{5,6}. These biomarkers are commonly found in colorectal, endometrial and other gastrointestinal cancers, but can also be present in other solid tumours⁷.

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 MSI-H/dMMR locally advanced rectal cancer. The trial was designed to assess clinical complete responses sustained for 12 months (cCR12) as determined by Independent Central Review, and to determine whether dostarlimab alone could enable patients to avoid chemotherapy, radiation and surgery. Additional efficacy outcomes include cCR12 based on investigator assessment and objective response rate (ORR), defined as patients who achieved cCR, clinical near-complete response, or clinical partial response as their best overall response. Patients received nine cycles of dostarlimab over six months, administered as a 500mg intravenous infusion every three weeks. The safety and tolerability profile of dostarlimab was generally consistent with its well-characterised safety profile observed across solid tumours. Serious adverse reactions occurred in 20% of patients receiving *Jemperli* and treatment was permanently discontinued due to adverse reactions in 3% of patients. The most common adverse reactions (≥15%) were fatigue, rash, diarrhoea, and pruritus.

About *Jemperli* (dostarlimab)

Jemperli, a programmed death receptor-1 (PD-1)-blocking antibody, plays an important role in GSK's immune-oncology 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 currently approved indications is available at [EU product information](#)⁸ and [US product information](#)⁹.

GSK in oncology

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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.

GSK enquiries

Media:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Sarah Clements	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Alison Hunt	+1 540 742 3391	(Washington DC)
	Stephanie Cacomo	+1 202 893 2840	(Washington DC)
Investor Relations:	James Dodwell	+44 (0) 7881 269066	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Joanna Tuplin	+44 (0) 7788 351650	(London)
	Sam Piper	+44 (0) 7824 525779	(London)
	Dan Smith	+44 (0) 7823 523885	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 3126	(Philadelphia)

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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Registered Office:

79 New Oxford Street
London
WC1A 1DG

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Memorial Sloan Kettering Cancer Center Disclosure: Dr Cercek has financial interests related to GSK.