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Jemperli (dostarlimab) data show 76% of patients with MSI-H/dMMR locally advanced rectal cancer achieved a complete response

- Patients had no evidence of cancer following treatment with Jemperli alone, confirmed by endoscopy, radiology and/or pathology
- No disease recurrences reported among responders after median follow-up of more than two years
- Data supported recent US approval of *Jemperli* in this indication
- Findings to be presented in a late-breaking oral session at ESMO

GSK plc (LSE/NYSE: GSK) today announced positive interim results from the phase II AZUR-1 trial evaluating *Jemperli* (dostarlimab) monotherapy as a standalone treatment approach in adults with stage II and III microsatellite instability-high (MSI-H)/mismatch repair deficient (dMMR) locally advanced rectal cancer. The results will be presented in a late-breaking oral session at the European Society for Medical Oncology (ESMO) Congress.

In an exploratory analysis, 76% of evaluable patients (110/144; 95% CI: 69%, 83%) achieved a complete response to dostarlimab alone. This included 68% (98/144; 95% CI: 60%, 76%) who achieved a sustained clinical complete response for at least 12 months (cCR12) without surgery as assessed by investigators, and 12 additional patients whose complete response was confirmed through tissue analysis showing no evidence of cancer following 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.

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}

Hesham Abdullah, Senior Vice President, Global Head of Oncology, R&D, GSK, said: “The AZUR-1 data demonstrate the potential for *Jemperli* alone to transform treatment for eligible patients with MSI-H/dMMR locally advanced rectal cancer. For some patients, avoiding chemotherapy, radiation and surgery may now be possible. The recent US approval of *Jemperli* is a major advance in how this disease may be treated for some patients.”

Dr Andrea Cercek, MD, Section Head of Colorectal Cancer and Co-Director of the Center for Young Onset Colorectal and Gastrointestinal Cancer, Memorial Sloan Kettering Cancer Center, and Principal Investigator of AZUR-1, said: “The AZUR-1 data presented show the global results of the high rate of non-operative management in patients with MSI-H/dMMR locally advanced rectal cancer treated with dostarlimab. The fact that there have been no disease recurrences to date after more than two years of follow-up should provide physicians with confidence in an organ preservation approach in this patient population.”

AZUR-1 met its primary objective, demonstrating that a clinically significant proportion of patients achieved cCR12. Data on the primary endpoint, cCR12 assessed by independent central review, continue to mature. At the time of analysis, 47% of evaluable patients (54/116; 95% CI: 37%, 56%) had achieved cCR12. An additional 38 participants had already achieved a clinical complete response but had not yet reached the 12-month assessment timepoint and remained under observation.

The safety profile of dostarlimab 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

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fatigue (32%), rash (22%), diarrhoea (18%) and pruritus (17%). Jemperi was permanently discontinued due to adverse reactions in 3% of patients.

Regulatory reviews are ongoing in participating countries through Project Orbis, an FDA Oncology Center of Excellence initiative designed to facilitate concurrent review by international health authorities.

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)¹. 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.^{2,3} These biomarkers are commonly found in colorectal, endometrial and other gastrointestinal cancers, but can also be present in other solid tumours.⁴

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 Jemperi and treatment was permanently discontinued due to adverse reactions in 3% of patients. The most common adverse reactions ($\geq 15\%$) were fatigue, rash, diarrhoea, and pruritus.

About Jemperi (dostarlimab)

Jemperi, 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 Jemperi 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.

Jemperi 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 *Jemperi*.

More information about the product and its currently approved indications is available at [EU product information](#)⁵ and [US product information](#).⁶

GSK in oncology

GSK develops differentiated medicines for cancers where advances in science and technology offer the greatest opportunity to improve patient outcomes across haematological, lung, gastrointestinal, genitourinary and gynaecological cancers. Across multiple modalities, including targeted small molecules, antibody-drug conjugates (ADCs) and immunotherapies, we apply deep expertise in cancer biology and immune system science to develop 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 Q2 Results for 2026.

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