# Stock-exchange announcement

For media and investors only

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# *Jemperli* (dostarlimab-gxly) 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

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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-gxly) 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 Commissioner's National Priority Voucher program, which could result in an earlier FDA decision.

Rectal cancer, a type of bowel cancer, affects around 770,000 people globally each year[1] and approximately 5-10% of cases have the dMMR/MSI-H subtype[2]. 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[3,4,5].

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 with no detectable signs of cancer for at least one year. In interim data, the safety and tolerability profile of dostarlimab-gxly was generally consistent with its well-characterized and manageable safety profile observed across solid tumors. 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[6]. The data support the potential for dostarlimab-gxly, 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-gxly to achieve clinical complete responses without other treatments in patients with dMMR/MSI-H locally advanced rectal cancer.

Dostarlimab-gxly was previously granted Fast Track and Breakthrough Therapy Designations in this setting[7,8]. 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[1]. Around 5–10% of rectal cancers are mismatch repair-deficient (dMMR) or microsatellite instability-high (MSI-H)[2]. These tumors 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-gxly[9,10]. These biomarkers are most commonly found in endometrial, colorectal 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-gxly 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-gxly alone could enable patients to avoid chemotherapy, radiation and surgery. Patients received nine cycles of dostarlimab-gxly over six months, administered as a 500mg intravenous infusion every three weeks. In interim data, the safety and tolerability profile of dostarlimab-gxly was generally consistent with its well-characterized and manageable safety profile observed across solid tumors.

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-gxly 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 immune-oncology based research and development program. A robust clinical trial program includes studies of *Jemperli* alone and in combination with other therapies in gynecologic, 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, commercialization and manufacturing of *Jemperli*.

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

**Indications and Important Safety Information for JEMPERLI (dostarlimab-gxly)**

- JEMPERLI, in combination with carboplatin and paclitaxel, followed by JEMPERLI as a single agent, is indicated for the treatment of adult patients with primary advanced or recurrent endometrial cancer (EC).
- JEMPERLI, as a single agent, is indicated for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced:
    - EC, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen in any setting and are not candidates for curative surgery or radiation, or
    - solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

**Important Safety Information**

**Severe and Fatal Immune-Mediated Adverse Reactions**

- Immune-mediated adverse reactions, which can be severe or fatal, can occur in any organ system or tissue and can occur at any time during or after treatment with a PD-1/PD-L1–blocking antibody, including JEMPERLI.
- Monitor closely for signs and symptoms of immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function tests at baseline and periodically during treatment. For suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.
- Based on the severity of the adverse reaction, withhold or permanently discontinue JEMPERLI. In general, if JEMPERLI requires interruption or discontinuation, administer systemic corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) until improvement to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic

immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids.

**Immune-Mediated Pneumonitis**

- JEMPERLI can cause immune-mediated pneumonitis, which can be fatal. In patients treated with other PD-1/PD-L1–blocking antibodies, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation. Pneumonitis occurred in 2.3% (14/605) of patients, including Grade 2 (1.3%), Grade 3 (0.8%), and Grade 4 (0.2%) pneumonitis.

**Immune-Mediated Colitis**

- Colitis occurred in 1.3% (8/605) of patients, including Grade 2 (0.7%) and Grade 3 (0.7%) adverse reactions. Cytomegalovirus infection/reactivation have occurred in patients with corticosteroid-refractory immune-mediated colitis. In such cases, consider repeating infectious workup to exclude alternative etiologies.

**Immune-Mediated Hepatitis**

- JEMPERLI can cause immune-mediated hepatitis, which can be fatal. Grade 3 hepatitis occurred in 0.5% (3/605) of patients.

**Immune-Mediated Endocrinopathies**

- Adrenal Insufficiency
    - Adrenal insufficiency occurred in 1.2% (7/605) of patients, including Grade 2 (0.5%) and Grade 3 (0.7%). For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment per institutional guidelines, including hormone replacement as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.
- Hypophysitis
    - JEMPERLI can cause immune-mediated hypophysitis. Grade 3 hypophysitis occurred in 0.4% (1/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel. Grade 2 hypophysitis occurred in 0.2% (1/605) of patients receiving JEMPERLI as a single agent. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.
- Thyroid Disorders
    - Grade 2 thyroiditis occurred in 0.5% (3/605) of patients. Grade 2 hypothyroidism occurred in 12% (30/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel. Grade 2 hypothyroidism occurred in 8% (46/605) of patients receiving JEMPERLI as a single agent. Hyperthyroidism occurred in 3.3% (8/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel, including Grade 2 (2.9%) and Grade 3 (0.4%). Hyperthyroidism occurred in 2.3% (14/605) of patients receiving JEMPERLI as a single agent, including Grade 2 (2.1%) and Grade 3 (0.2%). Initiate thyroid hormone replacement or medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.
- Type 1 Diabetes Mellitus, Which Can Present with Diabetic Ketoacidosis
    - JEMPERLI can cause type 1 diabetes mellitus, which can present with diabetic ketoacidosis. Grade 3 type 1 diabetes mellitus occurred in 0.4% (1/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel. Grade 3 type 1 diabetes mellitus occurred in 0.2% (1/605) of patients receiving JEMPERLI as a single agent. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.

**Immune-Mediated Nephritis with Renal Dysfunction**

- JEMPERLI can cause immune-mediated nephritis, which can be fatal. Grade 2 nephritis, including tubulointerstitial nephritis, occurred in 0.5% (3/605) of patients.

**Immune-Mediated Dermatologic Adverse Reactions**

- JEMPERLI can cause immune-mediated rash or dermatitis. Bullous and exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS), have occurred with PD-1/PD-L1–blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-bullous/exfoliative rashes. Withhold or permanently discontinue JEMPERLI depending on severity.

**Other Immune-Mediated Adverse Reactions**

- The following clinically significant immune-mediated adverse reactions occurred in <1% of the 605 patients treated with JEMPERLI or were reported with the use of other PD-1/PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.
  - *Nervous System*: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy
  - *Cardiac/Vascular*: Myocarditis, pericarditis, vasculitis
  - *Ocular*: Uveitis, iritis, other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur
  - *Gastrointestinal*: Pancreatitis, including increases in serum amylase and lipase levels, gastritis, duodenitis
  - *Musculoskeletal and Connective Tissue*: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica
  - *Endocrine*: Hypoparathyroidism
  - *Other (Hematologic/Immune)*: Autoimmune hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection, other transplant (including corneal graft) rejection

In**fusion-Related Reactions**

- Severe or life-threatening infusion-related reactions have been reported with PD-1/PD-L1–blocking antibodies. Severe infusion-related reactions (Grade 3) occurred in 0.2% (1/605) of patients receiving JEMPERLI. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion or permanently discontinue JEMPERLI based on severity of reaction.

**Complications of Allogeneic HSCT**

- Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after treatment with a PD-1/PD-L1–blocking antibody, which may occur despite intervening therapy. Monitor patients closely for transplant-related complications and intervene promptly.

**Embryo-Fetal Toxicity and Lactation**

- Based on its mechanism of action, JEMPERLI can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with JEMPERLI and for 4 months after their last dose. Because of the potential for serious adverse reactions from JEMPERLI in a breastfed child, advise women not to breastfeed during treatment with JEMPERLI and for 4 months after their last dose.

**Common Adverse Reactions**

The most common adverse reactions (≥20%), including laboratory abnormalities, in patients with EC who received JEMPERLI in combination with carboplatin and paclitaxel were decreased hemoglobin, increased creatinine, peripheral neuropathy, decreased white blood cell count, fatigue, nausea, alopecia, decreased platelets, increased glucose, decreased lymphocytes, decreased magnesium, decreased neutrophils, increased AST, arthralgia, rash, constipation, diarrhea, increased ALT, decreased potassium, decreased albumin, decreased sodium, increased alkaline phosphatase, abdominal pain, dyspnea, decreased appetite, increased amylase, decreased phosphate, urinary tract infection, and vomiting.

The most common adverse reactions (≥20%) in patients with dMMR EC who received JEMPERLI as a single agent were fatigue/asthenia, anemia, nausea, diarrhea, constipation, vomiting, and rash. The most common Grade 3 or 4 laboratory abnormalities (>2%) were decreased lymphocytes, decreased sodium, increased alanine aminotransferase, increased creatinine, decreased neutrophils, decreased albumin, and increased alkaline phosphatase.

The most common adverse reactions (≥20%) in patients with dMMR solid tumors who received JEMPERLI as a single agent were fatigue/asthenia, anemia, diarrhea, and nausea. The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocytes, decreased sodium, increased alkaline phosphatase, and decreased albumin.

**Please see the full US Prescribing Information for JEMPERLI, including Medication Guide.**

**GSK in oncology**
Our ambition in oncology is to help increase overall quality of life, maximize 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 tumors. This includes accelerating priority programs 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.us.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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