



Jemperli (dostarlimab) Approved in the U.S. as First and Only Immunotherapy for Adults with MSI-H/dMMR Locally Advanced Rectal Cancer

October 19, 2026

- Approval based on AZUR-1 data showing 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 2 years
- *Jemperli* monotherapy could help eligible patients avoid chemotherapy, radiation and surgery
- GSK to present full data from the AZUR-1 interim analysis as a late-breaking abstract at ESMO Congress 2026 in Madrid, Spain on October 25, 2026

SAN DIEGO, Oct. 19, 2026 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a company focused on managing the financial collaborations for *Jemperli* with Tesaro, a GSK company, and *Quimilza* (imsidolimab) with Vanda, today announced that GSK has received U.S. Food and Drug Administration (FDA) approval for *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.

Jemperli received FDA Fast Track and Breakthrough Therapy designations for this indication. The application was also granted Priority Review and received the National Priority Voucher, resulting in an accelerated approval ahead of the February 2027 PDUFA date.

This approval is supported by data from the AZUR-1 trial. The study met its primary objective, demonstrating a 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.

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 tumors. Serious adverse reactions occurred in 20% of patients receiving *Jemperli*, and the most common adverse reactions were fatigue (32%), rash (22%), diarrhea (18%) and pruritus (17%). *Jemperli* was permanently discontinued due to adverse reactions in 3% of patients.

GSK plans to present full data from the AZUR-1 interim analysis as a late-breaking abstract at ESMO Congress 2026 in Madrid, Spain on October 25, 2026.

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 tumors, a biomarker found in around 5-10% of rectal cancers, *Jemperli* monotherapy could help avoid these interventions.⁴

The AZUR-1 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 *Jemperli* (dostarlimab)

Jemperli is a programmed death receptor-1 (PD-1)-blocking antibody that binds to the PD-1 receptor and blocks its interaction with the PD-1 ligands PD-L1 and PD-L2. In the United States, *Jemperli* is currently approved for endometrial cancer, rectal cancer and dMMR solid tumors, and is currently being studied as monotherapy in colon cancer and head and neck squamous cell carcinoma.

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 conducting ongoing research, development, commercialization, and manufacturing of *Jemperli*.

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

About Anaptys

Anaptys manages the financial collaborations for *Jemperli* with GSK and *Quimilza* with Vanda, with a focus on protecting and returning the value of its royalties to shareholders. To learn more, visit www.AnaptysBio.com or follow us on [LinkedIn](#).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to future commercial and regulatory developments for *Jemperli* and *Quimilza*; and future royalty amounts. Statements including words such as “plan,” “continue,” “expect,” or “ongoing” and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements are subject to risks and uncertainties that may cause the company’s actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to commercial success of the Company’s licensed products, the company’s ability to protect its financial collaborations and return value to its shareholders, the company’s ability to operate efficiently with a limited staff, and other risks and uncertainties described under the heading “Risk Factors” in documents the company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and the company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

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 2. 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>
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 4. 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.

