

Jemperli Immunotherapy Continues to Show 100% Response Rate for Rectal Cancer

All rectal cancer patients with a specific genetic mutation had a complete response to the checkpoint inhibitor, and some were still in remission four years later.

July 10, 2024 By [Liz Highleyman](#)

All study participants with mismatch repair deficient (dMMR) rectal cancer achieved a clinical complete response when treated with the checkpoint inhibitor Jemperli (dostarlimab), according to a presentation at the [American Society of Clinical Oncology Annual Meeting \(ASCO 2024\)](#) in June. These results, for 42 patients, build on promising data from 12 patients reported at the same conference in 2022.

People who received Jemperli for six months as their first line of treatment had no visible remaining cancer and clear MRI scans, lead investigator Andrea Cercek, MD, of Memorial Sloan Kettering Cancer Center, reported. What's more, they were able to avoid surgery, chemotherapy and radiation.

"These findings demonstrate the potential of dostarlimab as a novel approach to treating locally advanced dMMR rectal cancer that leads to durable complete tumor regression without the need for life-altering treatment," Cercek said in a [GSK news release](#). "As a clinician, I've seen firsthand the debilitating impact of standard treatment of dMMR rectal cancer and am thrilled about the potential of dostarlimab in these patients."

Rectal cancer, an uncommon malignancy related to [colon cancer](#), is often diagnosed at a later stage, when it is more difficult to treat. Standard treatment for locally advanced rectal cancer is neoadjuvant (presurgery) chemotherapy and radiation to shrink tumors, followed by surgery to remove all or part of the rectum. (Rectal cancer is not the same as [anal cancer](#), which is caused by human papillomavirus and requires different screening and treatment approaches.)

A Phase II clinical trial ([NCT04165772](#)) enrolled adults with Stage II or III locally advanced dMMR rectal adenocarcinoma at Memorial Sloan Kettering in New York City. Normally, cells can fix mistakes that arise when DNA is copied during cell division, but dMMR tumors lack this mechanism, which means mutations accumulate and cells can grow out of control. This type of rectal cancer tends to respond poorly to chemotherapy but is susceptible to immunotherapy,

Cercek noted. Around 5% to 10% of colorectal tumors are mismatch repair deficient. This study highlights the importance of [genomic testing](#) to see whether patients have dMMR cancer and are likely to respond well.

Jemperli is a monoclonal antibody that targets PD-1, a receptor on T cells that regulates immune function. Some tumors can hijack PD-1 to turn off immune responses. Drugs that block the interaction between PD-1 and its receptor on cancer cells can release the brakes and restore T-cell activity. The Food and Drug Administration (FDA) [approved Jemperli in 2021](#) for advanced or recurrent dMMR endometrial cancer. The drug later received accelerated approval for [all advanced or recurrent dMMR solid tumors](#), regardless of location, that have progressed despite prior treatment.

This study tested Jemperli as a treatment for earlier-stage rectal cancer that is locally advanced but has not yet spread to other parts of the body and has not previously been treated with chemotherapy, immunotherapy or radiation. This indication is not yet FDA approved, but the National Comprehensive Cancer Network includes it in its guidelines.

About 60% of the study participants were women, three quarters were white and ages ranged from 26 to 78 years, Cercek said. Most had cancer-positive lymph nodes. About half had Lynch syndrome, a genetic condition that leads to mismatch repair deficiency and dramatically raises the risk of colorectal cancer.

All were treated with Jemperli alone, administered via IV infusion every three weeks for six months; there was no placebo or comparison therapy group. This initial treatment was originally intended to be followed by surgery, chemotherapy and radiation, but that turned out not to be necessary.

As reported [at the 2022 ASCO meeting](#) and in [The New England Journal of Medicine](#), all of the first 12 participants who finished Jemperli treatment and were followed for at least six months achieved complete remission. At this year's conference, Cercek reported that the clinical complete response rate is still 100% with 42 treated patients. This was defined as no remaining evidence of tumors according to endoscopy, digital rectal exams and MRI scans. In addition, circulating tumor DNA blood tests were negative and tumor biopsies were normal.

Jemperli was generally safe and well tolerated, and no one experienced severe adverse events or serious immune-mediated side effects that can sometimes occur with checkpoint immunotherapy.

None of the participants have had disease recurrence or required any further treatment. "We haven't radiated anybody, and we haven't put anybody through surgery. They have preserved normal bowel function, bladder function, sexual function, fertility," Cercek said in a [Memorial Sloan Kettering news report](#). With a median 26 months of follow-up, 24 patients had sustained complete responses that lasted at least one year, and many were still in remission at two years. "Most people on the trial have been free of cancer for at least a year, and the original participants have been healthy for up to four years and counting," she said. "The success rate remains 100%."

A multicenter open-label Phase II trial dubbed [AZUR-1](#) is now evaluating the efficacy and safety of Jemperi monotherapy for previously untreated patients with dMMR/MSI-H locally advanced rectal cancer as a replacement for chemotherapy, radiation and surgery. The treatment is also being studied for resectable Stage III colorectal cancer in the [AZUR-2](#) trial.

Click here to read the [study abstract](#).

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