

Agenus Reports 72% of Patients with Locally Advanced dMMR Colon Cancer Had No Cancer Remaining at Surgery Following Six Weeks of BOT+BAL in Phase 2 NEOASIS Study at ESMO 2026

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- The cohort met its primary endpoint of major pathologic response, with 83% of patients having little or no cancer remaining at surgery in a high-risk, locally advanced population
- Side effects were mostly mild and manageable, and all 18 patients proceeded to surgery
- Netherlands Cancer Institute investigators are now enrolling a rectal cancer cohort to evaluate whether a short course of botensilimab and balstilimab can allow patients to avoid surgery

LEXINGTON, Mass.--(BUSINESS WIRE)-- **Agenus Inc. (Nasdaq: AGEN)**, a leader in immuno-oncology innovation, today announced early Phase 2 results from the mismatch repair-deficient (dMMR) colon cancer cohort of NEOASIS, an investigator-initiated pan-tumor study sponsored by the Netherlands Cancer Institute (NKI). NEOASIS is evaluating botensilimab (BOT), Agenesis' multifunctional, Fc-enhanced anti-CTLA-4 antibody, in combination with balstilimab (BAL), Agenesis' anti-PD-1 antibody, given before surgery (neoadjuvant) in patients with solid tumors. The results were presented in a poster at the European Society for Medical Oncology (ESMO) Congress 2026 in Madrid, Spain.

The cohort met its primary endpoint, with 83% of 18 patients achieving a major pathologic response (MPR), defined as 10% or less viable tumor remaining at surgery, and 72% achieving a pathologic complete response (pCR), with no cancer remaining in the tumor or nearby lymph nodes.

These results were achieved in patients at the highest risk of their cancer returning. All patients had locally advanced colon cancer, and 100% of tumors were at least T3. Two-thirds (67%) were T4 tumors that had grown

through the bowel wall. Nearly three-quarters (72%) had cancer that had spread to nearby lymph nodes. Treatment was a short 6-week course of immunotherapy alone with one 50 mg dose of BOT and two 450 mg doses of BAL, given three weeks apart, followed by surgery within eight weeks.

For patients with locally advanced dMMR colon cancer, treatment today typically begins with surgery, followed by months of chemotherapy that may be combined with up to a year of PD-L1 immunotherapy. NEOASIS is evaluating a different approach, giving a short course of immunotherapy before surgery while the tumor and surrounding lymph nodes are still in place to help drive an immune response against cancer.

“Nearly three out of four patients with locally advanced disease, had no cancer remaining at surgery after a single dose of botensilimab and two doses of balstilimab,” said Myriam Chalabi, MD, PhD, principal investigator of the NEOASIS study at the Netherlands Cancer Institute. “These dMMR colon cancer results build on the responses we first reported across multiple tumor types in NEOASIS and support continued investigation of BOT+BAL before surgery. Our ongoing rectal cancer cohort is exploring whether deep responses like these, with a short duration of neoadjuvant BOT+BAL, can allow selected patients to preserve their organs and quality of life without compromising cancer outcomes.”

The dMMR colon cancer cohort builds on early NEOASIS results presented by Dr. Chalabi at the American Association for Cancer Research (AACR) Annual Meeting 2025, which showed responses before surgery across multiple solid tumor types in a safety run-in that evaluated BOT at 25 mg and 50 mg. Based on those results, the 50 mg dose was selected for this cohort.

Additional findings

- Responses: Nearly all patients (17 of 18) had a pathologic response at surgery.
- Follow-up: All patients were alive at a median follow-up of 15 months, and 16 of 18 remained free of recurrence.
- Organ preservation: One patient with both a colon and a rectal tumor had a complete response in the rectal tumor and chose to preserve the rectum instead of undergoing rectal surgery, with no signs of regrowth at seven months.
- Safety and surgery: Immune-related side effects were mostly Grade 1 or 2 and manageable. One patient had Grade 3 colitis, which resolved with treatment. Seventeen of 18 patients underwent surgery as planned; one patient had surgery earlier than planned, on Day 41, because of a bowel obstruction (ileus) and had a pathologic complete response.

NKI investigators are now enrolling a dMMR rectal cancer organ-preservation cohort within NEOASIS to evaluate whether BOT+BAL can allow patients to avoid surgery.

Agenus is advancing this short-course approach in microsatellite-stable (MSS) colon cancer, which makes up about 85% of early-stage colon cancer cases.

“These results show how much a short course of BOT+BAL can accomplish before surgery, even in patients whose cancer had already grown through the bowel wall or reached the lymph nodes,” said Steven J. O’Day, MD, Chief Medical Officer of Agenus. “Treating while the tumor and lymph nodes are still intact gives the immune system its best opportunity to eliminate the cancer. Our goal is a future where patients are treated for weeks rather than months, with less chemotherapy, a lower risk of recurrence and increase the more patients who may ultimately be cured.”

Outside of Armenia, BOT and BAL are investigational and have not been approved by the U.S. Food and Drug Administration.

The full poster is available at www.agenusbio.com/publications.

Presentation details

Abstract Title: Neoadjuvant botensilimab plus balstilimab in MMR deficient colorectal cancer: results from the NEOASIS study

Presenter: Emma van den Berg, MD; Netherlands Cancer Institute, Antoni van Leeuwenhoek Hospital, Amsterdam, Netherlands

Poster Presentation number: 837P

Session Title: Colon cancer

Date: Sunday, October 25, 2026

Time: 12:00 to 12:45 CET | 7:00 to 7:45 AM EDT

About the NEOASIS Study

NEOASIS (NCT06279130) is an investigator-initiated, single-center Phase 2 platform study sponsored by the Netherlands Cancer Institute evaluating neoadjuvant BOT+BAL in patients with resectable solid tumors, regardless of mismatch repair status. The dMMR colon cancer cohort enrolled 18 patients with non-metastatic, resectable disease, who received BOT 50 mg on Day 1, the dose selected following the study’s safety run-in, and BAL 450 mg on Days 1 and 22 before surgery. The primary endpoint was MPR, defined as 10% or less residual viable tumor. Agenus supplied BOT and BAL.

About Agenus

Agenus is a leading immuno-oncology company targeting cancer with a comprehensive pipeline of immunological agents. The company was founded in 1994 with a mission to expand patient populations benefiting from cancer immunotherapy through combination approaches, using a broad repertoire of antibody therapeutics, adoptive cell therapies (through MiNK Therapeutics) and adjuvants. Agenus has robust end-to-end development capabilities, across commercial and clinical cGMP manufacturing facilities, research and discovery, and a global clinical operations footprint. Agenus is headquartered in Lexington, MA. For more information, visit www.agenusbio.com or @agenus_bio. Information that may be important to investors will be routinely posted on our website and social media channels.

Agenus' Commitment to Patient Access

Agenus is committed to expanding patient access to BOT+BAL through regulatory approvals, clinical trials and authorized early-access pathways. Following the first marketing authorizations for Botvymo® (botensilimab) and Evamplix® (balstilimab) in Armenia for eligible adults with microsatellite stable (MSS) metastatic colorectal cancer without active liver metastases who have previously received available standard therapies, BOT+BAL remains investigational outside Armenia and is not approved by the U.S. Food and Drug Administration (FDA).

In France, the national Autorisation d'Accès Compassionnel (AAC) program provides fully reimbursed, hospital-based access to BOT+BAL for eligible patients with MSS metastatic colorectal cancer without active liver metastases, platinum-resistant or platinum-refractory ovarian cancer, and certain advanced soft-tissue sarcomas. In a growing number of other countries, BOT+BAL is available through physician-initiated named-patient programs under local regulations. BAP Pharma serves as Agenus' global partner for the French AAC pathway and named-patient access programs.

Physicians seeking information about authorized access pathways can visit the **Patient Access** section of the Agenus website.

About Botensilimab (BOT)

Botensilimab (BOT) is a human multifunctional, Fc-enhanced anti-CTLA-4 antibody designed to boost both innate and adaptive anti-tumor immune responses. Its novel design leverages mechanisms of action to extend immunotherapy benefits to "cold" tumors which generally respond poorly to standard of care or are refractory to conventional PD-1/CTLA-4 therapies and investigational therapies. BOT augments immune responses across a wide range of tumor types by priming and activating T cells, reducing intratumoral regulatory T cells, activating myeloid cells and inducing durable memory responses.

Approximately 1,500 patients have been treated with BOT and balstilimab (BAL) in phase 1 and phase 2 clinical

trials. The combination with Agenus' investigational PD-1 antibody, BAL, has shown clinical responses across more than nine cancers. For more information about BOT trials, visit www.clinicaltrials.gov.

About Balstilimab (BAL)

Balstilimab is a novel, fully human monoclonal immunoglobulin G4 (IgG4) designed to block PD-1 (programmed cell death protein 1) from interacting with its ligands PD-L1 and PD-L2. It has been evaluated in more than 900 patients to date and has demonstrated clinical activity and a favorable tolerability profile in several tumor types.

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding its botensilimab and balstilimab programs, expected regulatory timelines and filings, and any other statements containing the words "may," "believes," "expects," "anticipates," "hopes," "intends," "plans," "forecasts," "estimates," "will," "establish," "potential," "superiority," "best in class," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include, among others, the factors described under the Risk Factors section of our most recent Annual Report on Form 10-K for 2025, and subsequent Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission. Agenus cautions investors not to place considerable reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this press release, and Agenus undertakes no obligation to update or revise the statements, other than to the extent required by law. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.

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Source: Agenus Inc.