

Armenia Grants First Marketing Authorizations for Agenus' BOT+BAL in Previously Treated MSS Metastatic Colorectal Cancer

2026-10-08

- Botvymo® (botensilimab) and Evamplix® (balstilimab) receive separate approvals for use in combination
- Armenia is the first country to approve marketing authorization of BOT+BAL, following a rigorous review of quality, nonclinical, clinical and pharmacovigilance data
- Approvals supported by clinical evidence published in peer-reviewed journals and presented at major oncology congresses, including two-year Phase 1b survival findings and randomized Phase 2 data in MSS metastatic colorectal cancer without active liver metastases
- Agenus will evaluate the potential for approvals in other Eurasian Economic Union countries that support this regulatory path

LEXINGTON, Mass.--(BUSINESS WIRE)-- **Agenus Inc.** (Nasdaq: AGEN), a leader in immuno-oncology innovation, today announced that the Ministry of Health of the Republic of Armenia has granted marketing authorizations for Botvymo® (botensilimab, BOT) and Evamplix® (balstilimab, BAL), each approved for use in combination with the other for the treatment of adult patients with microsatellite stable (MSS) metastatic colorectal cancer (mCRC) without active liver metastases who have previously received available standard therapies. These are the first marketing authorizations for either medicine anywhere in the world. The approvals are expected to benefit patients in Armenia as well as patients who travel to Armenia for treatment under the care of Armenian oncologists.

Botensilimab is a multifunctional, Fc-enhanced anti-CTLA-4 antibody designed to activate innate and adaptive antitumor immune responses, including in tumors that have historically responded poorly to conventional immunotherapy. Balstilimab is an anti-PD-1 antibody designed to sustain antitumor T-cell activity.

The approvals are effective as of October 2, 2026. They follow a rigorous review by Armenia's regulatory authorities

of the complete registration dossier, submitted in the international Common Technical Document format used under Eurasian Economic Union rules. The review covered product quality and manufacturing (chemistry, manufacturing and controls), nonclinical data, clinical efficacy and safety data, and the pharmacovigilance system and risk management plan. BOT and BAL were separately submitted and approved for use as a combination regimen. Under the approved product information, Botvymo is administered at 75 mg intravenously every 6 weeks for up to 4 doses, in combination with Evamplix at 240 mg intravenously every 2 weeks for up to 2 years or until disease progression or unacceptable toxicity.

Each **marketing authorization** is conditional and valid for one year and is renewable based on the clinical updates that Agenus will provide to the Armenian regulator each year.

“Armenia is the first country in the world to grant marketing approval for BOT+BAL,” said Garo H. Armen, PhD, Chairman and Chief Executive Officer of Agenus. “The evidence behind this decision has been published in peer-reviewed journals and presented at major cancer conferences, and it has consistently pointed to clinical benefit for patients with metastatic colorectal cancer. We thank Armenia’s health authorities for the depth and care of their review. Patients who have exhausted standard treatments now have a new option, and we are proud to bring it to them.”

Clinical Evidence Supporting the Approvals

The Armenian approvals were based on the totality of clinical evidence for BOT+BAL in MSS mCRC, including mature results from the fully enrolled MSS mCRC patient cohort from the Phase 1b C-800-01 study and data from the randomized Phase 2 C-800-25 study. Results from this clinical program have been published in peer-reviewed journals, including **Nature Medicine** and **Clinical Cancer Research**, and presented at major oncology congresses, including the ASCO Gastrointestinal Cancers Symposium. The efficacy and safety data supporting the approvals are summarized in the approved product information for Botvymo and Evamplix.

Regional Opportunities

Following the Armenian approvals, Agenus will evaluate the potential to seek marketing authorizations for BOT+BAL in the MSS metastatic colorectal cancer setting in other Eurasian Economic Union member countries.

Access to BOT+BAL Outside Armenia

The Armenian marketing authorizations apply within the territory of Armenia.

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 our corporate website.

Important Safety Information

The approved product information for Botvymo and Evamplix includes warnings and precautions for immune-mediated adverse reactions, including colitis and diarrhea, hepatitis, pneumonitis, endocrinopathies, nephritis, myocarditis and pancreatitis, as well as infusion-related reactions. Healthcare professionals in Armenia should consult the approved product information before prescribing.

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.

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.

BOT+ balstilimab (BAL) has been studied in over 1,500 patients across more than nine tumor types, spanning late-

line refractory disease and early-stage neoadjuvant settings. The combination is being developed to expand immunotherapy benefit to more patients, including those with microsatellite stable (MSS) disease and tumors considered immunologically “cold” or resistant to existing immunotherapies. Agenus’ Phase 3 ROBBIN study is designed to evaluate BOT+BAL given before surgery in earlier-stage colon cancer.

For more information about botensilimab 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.

Botvymo and Evamplix are authorized in Armenia for use in combination for the treatment of previously treated MSS metastatic colorectal cancer without active liver metastases. Their use in other indications and in other countries remains investigational.

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, the conditional Armenian marketing authorizations and their renewal, the availability of treatment to patients who travel to Armenia, potential regulatory submissions in other countries, 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.

Investors

917-362-1370 | investor@agenusbio.com

Media

781-674-4422 | communications@agenusbio.com

Source: Agenus Inc.