

Agenus Reports 48% Estimated Three-Year Survival With BOT+BAL in Recurrent Ovarian Cancer at IGCS 2026

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- Survival estimate remained at 48% between years two and three, extending evidence of durable benefit
- Results observed in heavily pretreated, difficult-to-treat population that received a median of four prior lines of therapy; nearly three-quarters of patients had platinum-resistant or refractory cancer

LEXINGTON, Mass.--(BUSINESS WIRE)-- **Agenus Inc. (Nasdaq: AGEN)**, a leader in immuno-oncology innovation, today announced three-year follow-up results from the ovarian cancer cohort of its 400+ patient Phase 1b C-800-01 trial. The study evaluated botensilimab (BOT), Agenus' multifunctional, Fc-enhanced anti-CTLA-4 antibody, in combination with balstilimab (BAL), Agenus' anti-PD-1 antibody. The results, including three-year survival and outcomes by sensitivity to platinum-based chemotherapy and by prior treatment, were presented at the 2026 International Gynecologic Cancer Society (IGCS) Annual Global Meeting in Montréal, Canada.

Among patients evaluable for efficacy, three-year overall survival was 48% (n=35), unchanged from the two-year estimate, suggesting durable clinical benefit in this population. Responses and long-term survival were observed in both platinum-sensitive and platinum-resistant or refractory disease. At the last follow-up, 25% of patients who received at least one dose of treatment (11 of 44) were alive and off all therapy.

These results come from a population with substantial prior treatment. Patients had received a median of four prior lines of therapy, and 66% had received at least four. All had previously received platinum chemotherapy, 77% had received bevacizumab and 57% had received a PARP inhibitor. Nearly three-quarters had platinum-resistant or refractory disease, meaning their cancer had progressed during platinum treatment or returned within six months of it.

“In recurrent ovarian cancer, conventional checkpoint immunotherapy has rarely produced lasting benefit, particularly after the disease stops responding to platinum chemotherapy,” said Rebecca L. Porter, MD, of Dana-Farber Cancer Institute, who presented the data. “What stands out with longer follow-up is the survival plateau in patients who had already received multiple treatments. That pattern suggests that a different approach to activating the immune system may offer some patients lasting benefit, even when treatment options have narrowed.”

Three-year follow-up findings

Overall efficacy results (n=35)

- Overall survival (OS): Estimated survival was 48% at both two and three years. Median OS was 14.8 months.
- Objective response rate (ORR): 23% of patients (8/35) had a response, including one complete response and seven partial responses.
- Duration of response: Responses lasted a median of 9.7 months.
- Clinical benefit: 31% of patients (11/35) had a response or stable disease lasting at least 24 weeks.
- Alive and off treatment: At last follow-up, 25% (11 of all 44 patients who received at least one dose of treatment) were alive and off all therapy.

Results by patient subgroup

- Platinum-resistant or refractory disease (n=25): Estimated three-year survival was 47%. ORR was 20% (5/25), including one complete and four partial responses.
- Platinum-sensitive disease (n=10): Estimated three-year survival was 45%. Thirty percent (3/10) of patients had a partial response.
- Four or more prior lines of therapy (n=23): Estimated three-year survival was 48%. ORR was 17% (4/23), with all four responses being partial responses.
- Disease progression on a PARP inhibitor (n=17): In patients whose cancer had progressed during PARP inhibitor treatment or maintenance, estimated three-year survival was 61%. Two patients (12%) had partial responses.

Safety remained consistent with the known BOT+BAL profile. No new safety signals or treatment-related deaths were reported.

“The most compelling finding is that the survival curve extends beyond two years in women who had already received multiple treatments, including those with platinum-resistant or refractory disease,” said Steven J. O’Day, MD, Chief Medical Officer of Agenus. “We have seen a similar pattern of durable survival in other difficult-to-treat cancers studied with BOT+BAL. This three-year ovarian update strengthens our conviction that the

combination can deliver meaningful, lasting benefit to a subset of patients who have had few effective immunotherapy options.”

The three-year ovarian results add to a pattern of long-term survival across difficult-to-treat cancers studied with BOT+BAL. In the broader 400+ patient Phase 1b pan-tumor analysis, estimated two-year survival was 39%. In a separate cohort of patients with refractory MSS metastatic colorectal cancer without active liver metastases, estimated survival was 41% at two years and 33% at three years. These findings are particularly notable in cancers where conventional immunotherapy has historically offered limited benefit.

The consistent and durable BOT+BAL activity in heavily pretreated cancers that are poorly immunogenic or resistant to prior immunotherapy, reinforced by deep pathologic responses in neoadjuvant studies, strengthens the rationale for moving treatment earlier in the course of disease. Before surgery, when the primary tumor and surrounding lymph nodes remain intact, BOT+BAL may have the greatest opportunity to generate lasting antitumor immunity, reduce recurrence and ultimately increase the number of patients who may be cured.

The full presentation can be found on the publications section of the Agenus website at www.agenusbio.com/publications.

BOT and BAL are in development and have not been approved by the U.S. Food and Drug Administration.

Presentation details

Abstract Title: Next Generation Immune Checkpoint Inhibition with Botensilimab Plus Balstilimab in Recurrent Ovarian Cancer: Results by Platinum Sensitivity Status and 3-Year Overall Survival

Presenter: Rebecca L. Porter, MD; Dana-Farber Cancer Institute, Boston, MA, USA

Poster Presentation number: 969

Session Title: Poster Rounds with Professors Session, Ovarian Cancer 03 Session

Date/Time: Saturday, October 3, 2026 | 10:50am-10:55am EDT

About the C-800-01 Study

C-800-01 (NCT03860272) is a multicenter Phase 1b trial evaluating BOT with or without BAL in advanced solid tumors. The ovarian cancer cohort included patients with recurrent disease for whom no standard therapy was

available or whose cancer had progressed after standard treatment. The efficacy analysis included 35 patients who had at least one tumor scan after starting therapy. The safety population included all 44 patients who received treatment. The data cutoff for this analysis was December 13, 2025.

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

Until marketing authorization is granted, BOT+BAL is accessible only through clinical trials and authorized early access mechanisms where permitted and available under each country's regulatory framework. For eligible French patients treated in hospitals under AAC and meeting the predefined criteria, BOT+BAL is fully reimbursed by France's national health system. Outside France, access may be available in select countries through paid named-patient programs, which may involve out-of-pocket costs to the patient or coverage under applicable national or private reimbursement arrangements. These programs are physician-driven and are not promotional.

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.

Investors

917-362-1370 | investor@agenusbio.com

Media

781-674-4422 | communications@agenusbio.com

Source: Agenus Inc.