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NEWS RELEASE

Agenus Reports Phase II Data Demonstrating Immune Reprogramming and Durable Survival with Botensilimab, Balstilimab and agenT-797 in PD-1 Refractory Gastroesophageal Cancer

2026-04-17

- First study combining botensilimab (BOT) and balstilimab (BAL) with agenT-797 in gastroesophageal cancer shows disease control rate (DCR) of 77% in patients and long-term survival beyond 20 months in a subset of heavily pretreated patients
- Induction strategy linked to improvement in progression-free survival (PFS) and higher survival rates at 12 and 18 months, supported by evidence of immune activation and tumor reprogramming

LEXINGTON, Mass.--(BUSINESS WIRE)-- **Agenus** Inc. (Nasdaq: AGEN), a leader in immuno-oncology innovation, today announced data from an investigator-initiated Phase II trial at Memorial Sloan Kettering Cancer Center, investigating botensilimab (BOT) and balstilimab (BAL) in combination with agenT-797, MiNK's allo-iNKT cell therapy, ramucirumab and paclitaxel in patients with advanced PD-1 refractory gastroesophageal adenocarcinoma. The data are being presented at the American Association for Cancer Research (AACR) Annual Meeting, taking place April 17-22, 2026, in San Diego, CA.

This Phase II trial, which is the first to combine BOT and BAL with agenT-797 in patients with gastroesophageal cancer who progressed after frontline therapy, was designed to explore the role of immune priming and treatment sequencing. Patients received induction with agenT-797 (alone or plus BOT/BAL) followed by the full combination regimen, or initiated the combination without induction, with longitudinal biomarker sampling throughout. In this study (n=17), the regimen delivered a 77% DCR with long-term survival beyond 20 months in a subset, and the induction arm showed meaningful gains in PFS (6.9 vs. 3.5 months; HR 0.19; p=0.015) and OS (9.5 vs. 5.2 months), with 43% of induction-treated patients alive at both 12 and 18 months—underscoring that durability and survival

may be the most clinically relevant endpoints in this PD-1 refractory population.

“These findings illustrate the mechanistic synergy of agenT-797 with botensilimab and balstilimab in this PD-1 refractory setting,” said Dhan Chand, Ph.D., Vice President of Research at Agenus. “The induction approach promoted significant intratumoral infiltration of T cells and dendritic cells, the formation of organized tertiary lymphoid structures in on-treatment biopsy tissue from a patient with durable benefit, and activation of peripheral CD4 and CD8 T-cell populations. These changes are consistent with immune priming and tumor immune reprogramming, providing a biological rationale for the improved progression-free survival observed with the induction strategy.”

Efficacy findings from the Phase II (n=17) study included:

- DCR was observed in 77% of all treated patients, and long-term survival beyond 20 months was seen in a subset
- Patients who received induction cycle had longer progression-free survival (PFS) than those treated without induction, with median PFS of 6.9 months versus 3.5 months (HR 0.19; p=0.015), supporting the potential importance of immune priming and treatment sequencing.
- Median overall survival (OS) was 9.5 months in the induction cohort versus 5.2 months without induction, with 43% of induction-treated patients alive at both 12 and 18 months, compared with 20% and 0%, respectively, in the non-induction cohort.
- The study did not meet its primary endpoint of ORR; however, disease control and longer-term survival observed in a subset of patients support further study of this approach.

Correlative analyses showed that treatment with BOT, BAL, and agenT-797 was associated with significant intratumoral T cell and dendritic cell infiltration, the formation of organized tertiary lymphoid structures in on-treatment biopsies from a patient with prolonged benefit, and activation of peripheral CD4 and CD8 T cells.

The safety profile was consistent with the component agents. The most common treatment-emergent adverse events among all patients included fatigue, fever, diarrhea, anorexia, nausea and mucositis. Immune-related adverse events included dermatitis, colitis, gastritis, enteritis, hepatitis and hypothyroidism.

Additional analysis of the full biospecimen dataset is ongoing and is expected to provide further insight into immune mechanisms, optimal sequencing, and potential biomarkers that could help identify patients most likely to benefit.

Presentation Details:

Abstract Title: A phase II study of agenT-797, botensilimab (BOT) and balstilimab (BAL) in PD-1 refractory gastroesophageal cancer (GEC)

Presenter: Samuel L. Cytryn M.D.; Gastrointestinal Medical Oncologist, Memorial Sloan Kettering Cancer Center

Session Name: Phase II and Phase III Clinical Trials

Date/Time: April 20, 2026 | 2:00–5:00 PM PT; 5:00-8:00 PM EDT

Poster Section: 52

Abstract No.: CT166

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 Fc enhanced multifunctional 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. Botensilimab augments immune responses across a wide range of tumor types by priming and activating T cells, downregulating intratumoral regulatory T cells, activating myeloid cells and inducing long-term memory responses.

Approximately 1,200 patients have been treated with botensilimab and/or balstilimab in phase 1 and phase 2 clinical trials. Botensilimab alone, or in combination with Agenus’ investigational PD-1 antibody, balstilimab, has shown clinical responses across nine metastatic, late-line cancers. 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.

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.