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NEWS RELEASE

Agenus' BOT/BAL Neoadjuvant Pan-Cancer Data from the NEOASIS Study Presented in an Oral Session at AACR

2025-04-28

Initial results from NEOASIS demonstrate BOT/BAL efficacy in the neoadjuvant setting across multiple MSS and MSI-H solid tumors

LEXINGTON, Mass.--(BUSINESS WIRE)-- Agenus Inc. (Nasdaq: AGEN), a leader in immuno-oncology, today announced that data from the investigator sponsored NEOASIS study were presented in an oral session at the American Association for Cancer Research (AACR) Annual Meeting in Chicago, Illinois. This represents the third clinical study evaluating botensilimab and balstilimab (BOT/BAL) in the neoadjuvant setting, with outcomes reported in mismatch repair–proficient (pMMR/MSS) and mismatch repair–deficient (dMMR/MSI-H) solid tumors. These findings include the first reported outcomes with BOT/BAL outside colorectal cancer in the neoadjuvant setting.

"These initial results from the NEOASIS study indicate that botensilimab and balstilimab can induce pathological responses in patients with a variety of solid tumors, including triple-negative breast cancer, after just two doses," said Myriam Chalabi, MD, of the Netherlands Cancer Institute. "The observed response rates—achieved without dose-limiting toxicities or surgical delays—are notable."

NEOASIS Phase 2 Neoadjuvant BOT/BAL in Early-Stage Solid Tumors (NCT06279130)

Study Design:

The safety run-in enrolled patients with non-metastatic solid tumors, divided into two cohorts of 10 patients each: dMMR/MSI-H and pMMR/MSS. Patients received a single dose of BOT (25 mg or 50 mg) combined with BAL (450 mg) on Day 1 and again on Day 22.

Results:

- dMMR/MSI-H Cohort (9 colorectal, 1 duodenal cancer):
  - Pathological response rate: 90%
  - Major pathological response (MPR): 80%
  - Pathological complete response (pCR): 70%
- pMMR/MSS Cohort (6 triple-negative breast cancer, 2 ER+ breast cancer, 1 merkel cell carcinoma, 1 sarcoma):
  - Pathological response rate: 80%
  - Major pathological response (MPR): 70%
  - Pathological complete response (pCR): 20%
  - Triple-negative breast cancer subgroup (n=6): 63% achieved MPR

No dose-limiting toxicities were observed at either dose level, and all patients proceeded to surgery on schedule. Enrollment in the efficacy phase of the study continues.

"The NEOASIS study data reinforces earlier evidence of profound clinical activity with the BOT/BAL combination in the neoadjuvant treatment of solid tumors, including those traditionally resistant to immunotherapy," said Steven O'Day, MD, Chief Medical Officer at Agenus. "These findings substantiate the importance of this immunotherapy in early treatment settings and highlight the broad potential utility of this combination."

Presentation Details:

- Title: Neoadjuvant botensilimab plus balstilimab in MMR proficient and deficient early-stage cancers: First results of the pan-cancer NEOASIS study (NCT06279130)
- Presenter:Myriam Chalabi, MD, Netherlands Cancer Institute
- Session:Aiming for Cure: Adjuvant and Neoadjuvant Approaches
- Date and Time:April 28, 2025; 2:30 PM - 4:30 PM CT
- Abstract Number:CT130

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About Botensilimab (BOT)

Botensilimab is a human Fc enhanced CTLA-4 blocking 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.

Botensilimab alone, or in combination with Agenus' investigational PD-1 antibody, balstilimab, has shown clinical responses across nine metastatic, late-line cancers. Approximately 1,100 patients have been treated across the botensilimab/balstilimab program in phase 1 and phase 2 clinical trials. 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 >900 patients to date and has demonstrated clinical activity and a favorable tolerability profile in several tumor types.

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 (through SaponiQx). 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.

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 2024, 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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