

Agenus Announces Publication in the Journal of Clinical Oncology Highlighting Data from Botensilimab Plus Balstilimab in Relapsed/Refractory Metastatic Sarcomas

2025-01-29

LEXINGTON, Mass.--(BUSINESS WIRE)-- Agenesis Inc. (Nasdaq: AGEN), a leader in immuno-oncology, today announced publication in the Journal of Clinical Oncology showcasing data from its study of botensilimab (BOT) in combination with balstilimab (BAL) in patients with relapsed/refractory (R/R) metastatic sarcomas.

These findings further reinforce the consistency of the BOT/BAL combination, which has already shown activity and a favorable safety profile across both multiple “warm and cold” tumor types, including colon cancer, lung cancer, melanoma and ovarian cancers.

Patients with advanced sarcomas face poor outcomes and have limited treatment options, underscoring the urgent need for innovative therapies. This Phase 1 study evaluated the safety and efficacy of botensilimab (BOT), an Fc-enhanced anti-CTLA-4 antibody, in combination with balstilimab (BAL), an anti-PD-1 antibody, in this challenging patient population.

“The publication in the Journal of Clinical Oncology further underscores the significant potential of botensilimab and balstilimab to address ‘cold’ tumors like certain subtypes of refractory sarcomas,” said Dr. Breelyn A. Wilky, University of Colorado Cancer Center. “These findings highlight the ability of this combination to deliver meaningful clinical benefits, including durable responses and extended survival, for patients who previously had very limited treatment options.”

Publication Highlights

Study Overview

- This open-label multicenter trial (NCT03860272) enrolled patients across multiple sarcoma subtypes, including angiosarcoma and leiomyosarcoma—tumor types historically resistant to traditional checkpoint inhibitors. Patients were heavily pretreated with a median of three prior lines of therapy and 15% received previous PD(L)-1 therapy.
- In this expansion cohort, BOT was administered intravenously at 1 mg/kg or 2 mg/kg every 6 weeks in combination with BAL at 3 mg/kg every 2 weeks for up to 2 years.
 - All patients were evaluable for safety and 52 patients for efficacy.

Efficacy Highlights

- Durable responses were observed across immunologically "cold" soft tissue sarcoma types, including visceral angiosarcoma and leiomyosarcoma.
- Overall response rate (ORR) was 19.2% for the overall study population (n=52). Among angiosarcoma patients (n=18), ORR was 27.8%, with 33.3% in visceral and 22.2% in cutaneous subtypes.
- Disease control rate (DCR) was 65.4%, with a median progression-free survival (PFS) of 4.4 months and a 36% PFS rate at 6-months.
- At a median follow-up of 9.1 months, median overall survival (OS) was not reached; the 12-month OS was 69%.
- Median Duration of Response (DOR) of 21.7 months, underscoring durable efficacy in heavily pretreated patients.

Safety Highlights

- The BOT/BAL combination was well tolerated, with a manageable safety profile consistent with earlier findings across tumor types.
- The most common treatment-related adverse event (TRAE) was diarrhea/colitis (grade 3, 6.3%), generally managed successfully with early intervention using steroids and TNF-alpha inhibitors.
- No Grade 4 or 5 TRAEs were reported in this cohort.

These results add to a growing body of evidence supporting the potential of botensilimab plus balstilimab to deliver meaningful, durable benefit in multiple tumor types—especially those resistant to existing checkpoint inhibitors. As this data continues to show consistency and tolerability in colon, lung, melanoma, ovarian, and now sarcoma, it strengthens the rationale for broader investigation of this combination.

For more details, read the full publication in the Journal of Clinical Oncology [here](#).

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.

About Botensilimab (BOT)

Botensilimab (BOT) 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.

Approximately 1,100 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 with the identifiers NCT03860272, NCT05608044, NCT05630183, and NCT05529316.

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. 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.

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 2023, 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.