

Botensilimab/Balstilimab Clinical Responses in Refractory Sarcomas Presented at ESMO 2024

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BOT/BAL Demonstrates Broad and Durable Activity in Advanced Sarcoma Population

LEXINGTON, Mass.--(BUSINESS WIRE)-- Agenus Inc. ("Agenus") (Nasdaq: AGEN), a leader in developing novel immunological agents to treat various cancers, presented data today at the European Society for Medical Oncology (ESMO) Congress held in Barcelona, Spain. The data from a Phase 1 study of botensilimab (BOT), an investigational Fc-enhanced CTLA-4 inhibitor, in combination with balstilimab (BAL), an investigational PD-1 antibody, showed clinical activity in patients with refractory sarcomas, a population with limited treatment options.

"The continued activity with additional patients and longer follow-up of BOT/BAL in this study reinforces its potential as an important treatment option for patients with sarcomas," said Dr. Breelyn A Wilky, University of Colorado Cancer Center. "The deep and durable responses we are observing, particularly in late line patients with poorly immunogenic or 'cold' sarcomas like visceral angiosarcoma, leiomyosarcoma, and dedifferentiated liposarcoma, are significant. These findings highlight the potential of BOT/BAL to deliver extended survival and a meaningful clinical benefit for patients who previously had very limited options."

Study Highlights

- 64 patients with relapsed/refractory sarcomas (median of 3 prior lines of therapy) were treated with 1 or 2 mg/kg BOT + 3 mg/kg BAL.
- 52 patients were efficacy evaluable with at least one post-baseline 6-week imaging scan. ORR and DOR reporting will be based on the unconfirmed response in this cohort.
- Majority of sarcoma subtypes included angiosarcoma (39%) and leiomyosarcoma (34%).

Clinical Findings

- 23% overall response rate (ORR) was observed in the full sarcoma cohort, with a median duration of response (DOR) of 21.7 months. 12-month overall survival (OS) was 69% and the median OS was not reached.
- 39% ORR achieved in the angiosarcoma subtype (33% in cutaneous and 44% in visceral), with a median DOR of 21.7 months. 12-month OS was 64% and the median OS was not reached.
 - A representative patient with visceral angiosarcoma achieved a durable response, ongoing beyond 3 years, that has been maintained off-therapy.
- The adverse event profile of BOT+ BAL was manageable and reversible with no new safety signals identified.

"The updated sarcoma data presented at ESMO underscore the transformative potential of botensilimab and balstilimab for patients with refractory sarcomas who have exhausted other treatment options," said Dr. Steven O'Day, Chief Medical Officer at Agenus. "Seeing these metastatic sarcoma patients experience tumor reduction, with significant and durable responses is incredibly encouraging. BOT/BAL not only offers hope to patients with sarcoma but also holds promise for redefining the standard of care across other historically IO-resistant cancers."

The presentation is available on the Agenus website at <https://agenusbio.com/publications>.

About Botensilimab

Botensilimab is an investigational 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.

Approximately 1,100 patients have been treated with botensilimab 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 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 is 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 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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