Agenus' Botensilimab in Combination with Balstilimab Shows 33% Durable Responses in Ovarian Cancer

March 27, 2023

Data presented at plenary session of Society of Gynecologic Oncology Meeting

- Patients treated suffered from platinum resistant/refractory ovarian cancer
- Previous PD-(L)1/CTLA-4 combinations have reported only 3-10% responses in comparable patient populations[1,2]
- Findings consistent with botensilimab/balstilimab benefit in cold and refractory tumors across 9 different solid tumor cancers

LEXINGTON, Mass.--(BUSINESS WIRE)--Mar. 27, 2023-- Agenus Inc. (Nasdaq: AGEN), an immuno-oncology company with a pipeline of immunological agents targeting cancer and infectious disease, today announced results from a cohort of 24 evaluable patients in an expansion of the Company's Phase 1b study of botensilimab (multifunctional CTLA-4 antibody) in combination with balstilimab (PD-1 antibody) in patients with recurrent platinum resistant/refractory ovarian cancer. These findings, presented in an oral plenary session at the Society of Gynecologic Oncology (SGO) 2023 Annual Meeting on Women's Cancer, showed a 33% overall response rate (ORR).

"These results add to the growing body of data showing deep and durable efficacy signals for botensilimab across nine cold and treatment-resistant cancers," said Steven O'Day, M.D., Chief Medical Officer of Agenus. "Botensilimab is designed with a unique mechanism of action that stimulates both innate and adaptive immune responses against cancer, resulting in an improved benefit compared to what has been reported for other checkpoint therapies."

"The combination of botensilimab and balstilimab in platinum-resistant ovarian cancer shows promise for a substantial improvement in efficacy compared to existing therapies, which typically only yield single-digit response rates," said Bruno Bockorny, M.D., Harvard Medical School, Beth Israel Deaconess Medical Center, and principal investigator for the study. "The remarkable efficacy and manageable tolerability profile of this combination suggest a transformative potential for ovarian cancer patients."

The ovarian cancer cohort is part of a large study evaluating the safety, efficacy, and dose optimization of botensilimab alone and in combination with balstilimab in multiple solid tumors. Agenus is currently enrolling in Global Phase 2 ACTIVATE trial programs in metastatic microsatellite stable colorectal cancer, melanoma and pancreatic cancers. Based on recent positive findings presented at SITC, Agenus is also expanding enrollment of its anti-PD-(L)1 relapsed/refractory non-small cell lung cancer cohort of the Phase 1b study and planning additional NSCLC studies.

Study Design and Highlights

A total of 24 evaluable patients with recurrent platinum resistant/refractory ovarian cancer received either 1 or 2 mg/kg botensilimab every 6 weeks and 3 mg/kg balstilimab every 2 weeks.

Patient Demographics

- 79% were high grade serous, which has a poor prognosis
- Patients were heavily pre-treated, with a median of 4 prior lines of therapy including 21% with prior immunotherapy
- Majority of patients had biomarkers associated with poor response to immunotherapy:
  - 90% had a low tumor mutation burden (<10 mutations per megabase)
  - Over half of patients were PD-L1 negative by IHC

Clinical Findings

- 33% overall response rate (1 complete response, 7 partial responses)
  - Other PD-(L)1 + CTLA-4 combinations in other trials reported 3-10% response rates in a comparable patient population.[1,2]
- 67% disease control rate
- Median duration of response not reached
- Manageable tolerability profile

Presentation Details

Abstract Title: Botensilimab, a Novel Innate/Adaptive Immune Activator, plus Balstilimab (Anti-PD-1) in Patients with Recurrent Platinum Refractory/Resistant Ovarian Cancer (NCT03860272)

Presenting Author: Bruno Bockorny, MD, Harvard University, Beth Israel Deaconess Medical Center

Data presented will be available to view in the Publications section of the Agenus website (https://agenusbio.com/publications) following the SGO Conference.

References

1 https://clinicaltrials.gov/ct2/show/results/NCT01928394
2 Hinchcliff et al. Gynecologic Oncology 2021

About Botensilimab

Botensilimab is a novel, multifunctional CTLA-4 investigational antibody that has been designed to extend clinical benefits to “cold” tumors that have not historically responded to standard of care or investigational therapies. In addition to binding to the CTLA-4 receptor, its Fc-enhanced structure induces a memory immune response, downregulates regulatory T cells, and delivers better priming and activation of T cells, thereby amplifying immune responses.

In a Phase 1b clinical study of more than 300 patients, botensilimab has demonstrated clinical responses in nine solid tumor cancers, either alone or in combination with Agenus’ PD-1 antibody, balstilimab. Agenus is conducting global, randomized Phase 2 trials in microsatellite-stable colorectal cancer (MSS CRC), pancreatic cancer, and melanoma as part of its ACTIVATE trial program. Additional information about these botensilimab trials can be found at www.clinicaltrials.gov under the identifiers NCT05608044, NCT05630183, and NCT05529316, respectively. A global Phase 3 trial in MSS CRC is expected to launch in 2023.

About Agenus
Agenus is a clinical-stage immuno-oncology company focused on the discovery and development of therapies that engage the body's immune system to fight cancer and infections. The Company's vision is to expand the patient populations benefiting from cancer immunotherapy by pursuing combination approaches that leverage a broad repertoire of antibody therapeutics, adoptive cell therapies (through its subsidiary MiNK Therapeutics), and adjuvants (through its subsidiary SaponiQx). The Company is equipped with a suite of antibody discovery platforms and a state-of-the-art GMP manufacturing facility with the capacity to support clinical programs. Agenus is headquartered in Lexington, MA. For more information, please visit www.agenusbio.com and our Twitter handle @agenus_bio. Information that may be important to investors will be routinely posted on our website and Twitter.

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 relating to our technologies, therapeutic candidates, and capabilities, for instance, statements regarding therapeutic benefit and efficacy, mechanism of action, potency, durability, and safety and tolerability profile of our therapeutic candidates, both alone and in combination with each other and/or other agents; statements regarding future plans, including research, clinical, regulatory, and commercialization plans; and any other statements containing the words "may," "believes," "expects," "anticipates," "hopes," "intends," "plans," "will" 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 Quarterly Report on Form 10-Q or Annual Report on Form 10-K filed with the Securities and Exchange Commission and available on our website: www.agenusbio.com. 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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