Agenus Data at CTOS 2022 Highlight Durable Clinical Responses of Botensilimab / Balstilimab Combination in Advanced Sarcoma

November 17, 2022

- Overall response rate (ORR) of 46% and disease control rate (DCR) of 69% in heavily pre-treated patients who have received a median of 3 prior lines of therapy
- Patient responses include sarcoma subtypes that historically do not respond to immunotherapy, including responses in 3 of 4 patients with visceral angiosarcoma
- 67% of patient responses have exceeded one year and remain ongoing at data cut-off
- Phase 2 trial of botensilimab/balstilimab in sarcomas planned for 2023

LEXINGTON, Mass., Nov. 17, 2022 (GLOBE NEWSWIRE) -- Agenus (Nasdaq: AGEN), an immuno-oncology company with a broad pipeline targeting cancer and infectious disease, announced expanded data from the Company's Phase 1 study of botensilimab (Fc-enhanced anti-CTLA-4) and balstilimab (anti-PD-1) in patients with advanced sarcoma. The data demonstrate that the combination offers strong durability and superior efficacy compared to what has been reported in separate trials for standard of care and other investigational therapies in sarcoma, including in sarcoma subtypes historically unresponsive to immunotherapy. The results will be presented tomorrow in an oral presentation at the Connective Tissue Oncology Society (CTOS) 2022 Annual Meeting in Vancouver, BC, Canada.

"The superior efficacy and durable responses achieved with botensilimab and balstilimab in advanced sarcoma build on the unprecedented clinical responses we have observed with this combination in multiple cold, treatment-resistant cancers," said Steven O'Day, MD, Chief Medical Officer at Agenus. "We are advancing multiple randomized Phase 2 trials to evaluate the therapeutic potential of this agent across a range of solid tumors."

Study Design and Highlights:

A total of 13 evaluable patients with advanced sarcoma received either 1 or 2 mg/kg botensilimab every 6 weeks and 3 mg/kg balstilimab every 2 weeks.

Patient Demographics:

- Heavily pre-treated, with a median of 3 prior lines of therapy
- 31% had received prior immunotherapy
- 82% had a known tumor mutation burden of less than 10 mutations per megabase
- Majority were PD-L1 negative by IHC

All of these biomarkers are associated with poor response to immunotherapy.

The botensilimab/balstilimab combination produced superior responses and strong durability relative to what has been reported in separate trials for standard of care and other combinations currently in development.

Objective responses:

- 46% overall response rate
  - Other PD-(L)1 + CTLA-4 combinations in a comparable patient population achieved only 12-16% response rates[1,2]
- 69% disease control rate (complete response + partial response + stable disease)

Durability:

- 67% objective responses ongoing at data cut-off
- Median duration of response has not been reached

Survival:

- 12-month overall survival of 77%
- Median overall survival has not been reached

Patient Sub-Populations:

- Objective response rate of 56% and disease control rate of 78% in 9 patients with angiosarcoma, including 3 of 4 patients

with visceral angiosarcoma
    - Other PD-(L)1 + CTLA-4 combinations achieved only 20-25% response rates in patients with angiosarcoma, with no reported responses in 7 patients with visceral angiosarcoma[2,3]
- Responses observed in additional patients with sarcoma subtypes historically resistant to immunotherapy, including liposarcoma with leiomyosarcomatous differentiation

Tolerability:

- Botensilimab was well tolerated; no grade 4 or 5 treatment-related adverse events in this cohort
- Safety profile similar to what has been previously reported in the Phase 1 botensilimab program, with no new immune-mediated safety signals observed

“At present, available treatments for advanced soft tissue sarcoma patients only have modest activity, and response rates for other immunotherapy combinations for most types of sarcoma are well below 20 percent,” said Breelyn Wilky, MD, Principal Investigator and Director of Sarcoma Medical Oncology at the University of Colorado School of Medicine. “The clinical responses demonstrated by botensilimab and balstilimab in this study are compelling and support plans for further development of this combination in sarcoma.”

Presentation Details:

Abstract Number: 1294633

Abstract Title: Results from a Phase 1a/1b Study of Botensilimab (a Novel CTLA-4 Engager) Plus Balstilimab (Anti-PD-1 Antibody) for the Treatment of Patients with Advanced Sarcomas

Presenting Author: Breelyn A. Wilky, MD, Director of Sarcoma Medical Oncology, Deputy Associate Director for Clinical Research, University of Colorado Cancer Center

The data will be presented on November 18th at 4:15 PM PDT in an oral presentation at the Connective Tissue Oncology Society (CTOS) 2022 Annual Meeting in Vancouver, BC, Canada. An archived version of the presentation will be available on the Agenus website at agenusbio.com.

References

1 D’Angelo et al. Lancet Oncology 2018
2 Somaiah et al. Lancet Oncology 2022
3 Wagner et al JITC 2021

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 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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