Agenus Presents Clinical Data Demonstrating Durable Responses of Botensilimab/Balstilimab Combination in Metastatic Microsatellite Stable Colorectal Cancer at ASCO GI

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- Overall response rate (ORR) of 23% and disease control rate (DCR) of 76% in expanded cohort of 70 heavily pre-treated patients; data suggest superior benefit compared to what has been reported for standard of care and other investigational therapies
- Responses have been durable with 69% ongoing at data cut-off; median overall survival not reached
- Global, randomized Phase 2 trials of botensilimab/balstilimab in MSS CRC and other indications have commenced; plan to initiate Phase 3 CRC trial in 2023

LEXINGTON, Mass., Jan. 23, 2023 (GLOBE NEWSWIRE) -- Agenus (Nasdaq: AGEN), an immuno-oncology company with a pipeline of immunological agents targeting cancer and infectious disease, today announced clinical data from the MSS CRC (microsatellite stable colorectal cancer) 70 patient cohort of a Phase 1b study of botensilimab (multifunctional Fc-enhanced anti-CTLA-4) in combination with balstilimab (anti-PD-1) in patients with chemotherapy and/or immunotherapy-resistant tumors. The larger dataset continues to demonstrate that this combination offers superior efficacy and durability compared to what has been reported for standard of care and other investigational therapies in third line metastatic MSS CRC. The data were presented in the opening late-breaking oral session at the American Society of Clinical Oncology – Gastrointestinal Cancers Symposium (ASCO GI) in San Francisco, CA on Saturday Jan 21 2023.

“This data highlight the deep and durable responses achieved with botensilimab and balstilimab in advanced MSS CRC, underscoring remarkable benefit for these patients who have failed standard of care or other investigative therapies. With over 300 patients enrolled to date, botensilimab alone and in combination with balstilimab have demonstrated durable clinical responses across nine cold and treatment-resistant cancers,” said Steven O’Day, MD, Chief Medical Officer at Agenus. “Our top priority is to advance this combination in global randomized trials with the intent to bring this important treatment to patients expeditiously.”

“MSS CRC accounts for over 95% of metastatic CRC cases and is characterized by tremendous unmet need, as available treatments have reported single digit responses rates,” said Anthony El-Khoueiry, MD, Phase I Program Director and Associate Director for Clinical Research at the USC Norris Comprehensive Cancer Center, Keck Medicine of USC, and the Principal Investigator for the study. “The 23% response rate demonstrated by botensilimab plus balstilimab in this study supports rapid development of this combination in MSS CRC.”

Study Design and Highlights:

A total of 70 evaluable patients with refractory metastatic MSS CRC 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 4 prior lines of therapy
- 31% had received prior immunotherapy

Objective responses:

- 23% overall response rate
  - Other PD-(L)1 + CTLA-4 combinations in comparable patient populations have reported 1-5% response rates[1,2]
- 69% of objective responses were ongoing at data cut-off
- 76% disease control rate (complete response + partial response + stable disease)

Survival:

- 12-month overall survival of 63%
  - Reported 12-month overall survival for standard of care is ~25%
- Median overall survival has not been reached

Tolerability:

- Manageable gastrointestinal toxicity with a differentiated overall safety profile

Presentation Details:

Abstract Title: Results from a phase 1a/1b study of botensilimab (BOT), a novel innate/adaptive immune activator, plus balstilimab (BAL; anti-PD-1 antibody) in metastatic heavily pretreated microsatellite stable colorectal cancer (MSS CRC) (NCT03860272)

Abstract Number: LBA8

Presenting Author: Anthony El-Khoueiry, MD, Phase I Program Director at the USC Norris Comprehensive Cancer Center, Keck Medicine of USC

Following the symposium, an archived version of the presentation will be available in the Publications section of the Agenus website at www.agenusbio.com.

References

1 Chen et al. JAMA Oncol. 2020

2 Overman et al. ASCO 2016

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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