Agenus Shows Unprecedented Activity for Botensilimab/Balstilimab Combination in Microsatellite Stable Colorectal Cancer at ESMO World GI Congress

June 29, 2022

- Overall response rate of 24%, and disease control rate of 73%, in heavily pre-treated patients with a median of 4 prior lines of therapy
- Responses to botensilimab/balstilimab were durable, with 80% ongoing at data cut-off and median duration of response not reached
- Global, randomized Phase 2 study of botensilimab/balstilimab in MSS CRC to begin this year
- Agenus to host webcast today at 10:00 AM EDT

LEXINGTON, Mass., June 29, 2022 (GLOBE NEWSWIRE) -- Agenus (NASDAQ: AGEN), an immuno-oncology company with an extensive pipeline of therapeutics designed to activate the immune response to cancers and infections, today announced expanded data from the Phase 1b study of botensilimab (Fc-enhanced anti-CTLA-4) and balstilimab (anti-PD-1) in patients with microsatellite stable colorectal cancer (MSS CRC). The data demonstrate that the combination offers strong durability and superior efficacy than what has been reported in separate trials for standard of care and other investigational therapies in 2L+ MSS CRC.

“These data reinforce the strong therapeutic potential of botensilimab, when used in combination with balstilimab, in cold tumors such as MSS CRC,” said Steven O’Day, MD, Chief Medical Officer at Agenus. “Thus far, botensilimab has demonstrated activity in nine cold and treatment-resistant cancers, and we plan to initiate a robust, global Phase 2 program, including in MSS CRC, later this year.”

Study Highlights

A total of 41 evaluable patients with metastatic MSS CRC received either 1 or 2 mg/kg botensilimab Q6W, and 3 mg/kg balstilimab Q2W. Patients were heavily pre-treated, with a median of 4 prior lines of therapy, and 34% had received prior 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:

- 24% overall response rate
- 73% disease control rate (partial response + stable disease)
- 50% objective responses with greater than 50% tumor reduction

Durability:

- 80% objective responses ongoing at data cut-off
- 30% objective responses exceeding 1 year

Patient Sub-Populations:

- Objective responses in 5 patients with RAS mutations for a 24% overall response rate and 81% disease control rate in this population; other PD-1 combinations in separate trials have reported only rare responses in this population (≤1% response rate)
- Responses observed in patients with metastases historically resistant to immunotherapy, including patients with malignant pleural effusions, soft tissue, peritoneal, retroperitoneal, and bone metastases

Tolerability:

- Botensilimab was well tolerated, with no grade 4/5 treatment-related adverse events
- Rates of gastrointestinal and skin toxicities were comparable to those reported with first-generation CTLA-4 inhibitors

“Colorectal cancer is the second leading cause of cancer-related death worldwide, with roughly 95% classified as microsatellite stable and historically unresponsive to immunotherapy. Treatment resistant MSS CRC patients lack effective options, with standard of care offering only a 1-2% response rate and a median expected survival ranging from 6 to 7 months,” said Anthony El-Khoueiry, MD, Phase I Program Director at the USC Norris Comprehensive Cancer Center, Keck Medicine of USC. “The combination of robust response rate, durability, and tolerability demonstrated by

botensilimab and balstilimab supports further development of the combination in MSS CRC, as well as more broadly, in other cold and treatment-resistant tumors."

Presentation Details

The data were presented today at 7:05 AM EDT in a late-breaking oral presentation at the ESMO World Congress on Gastrointestinal Cancer in Barcelona, Spain.

Abstract Title: Botensilimab, a Novel Innate/Adaptive Immune Activator, Plus Balstilimab (Anti-PD-1) for Metastatic Heavily Pretreated Microsatellite Stable Colorectal Cancer

Abstract Number: LBA-09

Presenting Author: Dr. Anthony El-Khoueiry, M.D., Associate Director of Clinical Research at the USC Norris Comprehensive Cancer Center, Keck School of Medicine

Investor Webcast

The Company will host an investor webcast today at 10:00 AM EDT to review these data. Participants may register here, or on the Investors section of the Agenus website at investor.agenusbio.com. The webcast will include presentations by the below speakers and will be followed by a Q&A session:

- Steven O'Day, M.D., Agenus' Chief Medical Officer
- Dr. Anthony El-Khoueiry, M.D., Associate Director of Clinical Research at the USC Norris Comprehensive Cancer Center, Keck School of Medicine
- Dr. Manuel Hidalgo, Chief of the Division of Hematology and Medical Oncology at Weill Cornell Medicine/NewYork-Presbyterian Hospital, and
- Dr. Heinz-Josef Lenz, M.D., Professor of Medicine and J. Terrence Lanni Chair in Gastrointestinal Cancer Research, Keck School of Medicine

Following the webcast, an archived version will be available on the Agenus website.

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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