Agenus Receives Fast Track Designation for Botensilimab and Balstilimab in Colorectal Cancer

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LEXINGTON, Mass.--(BUSINESS WIRE)--Apr. 17, 2023-- Agenus Inc. (Nasdaq: AGEN), a leading immuno-oncology company specializing in immunological agents for cancer and infectious diseases, has been granted Fast Track Designation from the US Food and Drug Administration (FDA) for the investigation of the combination of botensilimab (AGEN1181) and balstilimab (AGEN2034). The designation is for patients with non-microsatellite instability-high (MSI-H)/deficient mismatch repair (dMMR) metastatic colorectal cancer with no active liver involvement. Patients targeted with this designation are heavily pretreated are resistant or intolerant to a fluoropyrimidine, oxaliplatin, and irinotecan, and who have also received a VEGF inhibitor, an EGFR inhibitor and/or a BRAF inhibitor, if indicated. The company is conducting a global, randomized Phase 2 trial of botensilimab in combination with balstilimab compared to standard of care in non-microsatellite instability-high (non-MSI-H) colorectal cancer patients.

"We are pleased that the FDA has granted Fast Track designation for the combination of botensilimab with balstilimab in patients with non-MSI-H colorectal cancer, recognizing the high unmet medical need in this population," said Dr. Steven O'Day, Chief Medical Officer of Agenus. "The Fast Track designation offers important benefits, including the potential eligibility for a Priority Review, and we will be working with the FDA and all key stakeholders to rapidly advance the botensilimab/balstilimab combination in colorectal cancer as well as other solid tumor indications."

During the American Society of Clinical Oncology – Gastrointestinal Cancers Symposium in January 2023, Agenus presented positive results from its ongoing clinical trials of the botensilimab/balstilimab combination in patients with non-MSI-H colorectal cancer. The combination therapy showed an overall response rate of 23% and a 12-month survival rate of 63%, which compares to very limited activity of 1-2% overall response rate and ~25% 12-month survival rate reported for the standard of care. Responses to the botensilimab/balstilimab therapy have been durable, with 69% ongoing at data cut-off, and median overall survival not reached.

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 350 patients, botensilimab has demonstrated clinical responses in nine, previously IO unresponsive, solid tumor cancers, either alone or in combination with Agenus' PD-1 antibody, balstilimab (data presented at ASCO GI 2023, SGO 2023, CTOS 2022, SITC 2022). Agenus is conducting global, randomized Phase 2 trials in non-MSI-H colorectal cancer, pancreatic cancer, and melanoma as part of its ACTIVATE trial programs. 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 non-MSI-H 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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Zack Armen
Head of Investor Relations
917-362-1370
zack.armen@agenusbio.com

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