

Agenus Announces First Patient Enrolled in Global Phase 3 BATTMAN Trial of BOT+BAL Immunotherapy Combination in MSS or pMMR Metastatic Colorectal Cancer

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- A Landmark Registrational Study Aiming to Redefine Outcomes in MSS mCRC Which Represents Approximately 95% of Metastatic Colorectal Cancer Cases
- Colorectal Cancer Has Become the Leading Cause of Cancer-related Death in Adults Under Age 50

LEXINGTON, Mass.--(BUSINESS WIRE)-- **Agenus Inc.** (Nasdaq: AGEN), a leader in immuno-oncology innovation, today announced that the first patient has been enrolled in the landmark global phase 3 BATTMAN (CO.33) trial (NCT07152821). This study is evaluating Agenus' immunotherapy combination of botensilimab (BOT) plus balstilimab (BAL) versus best supportive care in patients with refractory, unresectable microsatellite stable (MSS)/mismatch repair proficient (pMMR) metastatic colorectal cancer (mCRC), a population long considered resistant to immunotherapy.

This study is being conducted as a cooperative group trial led by the Canadian Cancer Trials Group (CCTG) from Canada and run across Canada, France, Australia and New Zealand. More than 100 sites will participate across the academic cooperative networks of CCTG, GI Cancer Trials in Australia and France's Partenariat de Recherche en Oncologie Digestive (PRODIGE) consortium (including Unicancer, GERCOR and FFCD). The BATTMAN (CO.33) trial serves as the registrational-enabling study for BOT+BAL enrolling approximately 830 patients and is expected to complete global enrollment quickly, reflecting the unprecedented investigator and patient enthusiasm worldwide, including strong interest from sites and physicians engaged through Agenus' paid named patient and French AAC access programs.

“Enrollment of the first patient in the BATTMAN study marks a key milestone for Agenus and the BOT+BAL program,” said Dr. Steven O’Day, Chief Medical Officer, Agenus. “This study advances our goal of developing effective immunotherapies for patients who currently have few options. We’re grateful to our partners at CCTG, GI Cancer Trials in Australia, and PRODIGE and to the dedicated investigators, site staff, and patients driving this global effort.”

“Our collaboration with Agenus builds on years of cooperative-group research aimed at bringing immunotherapy benefits to patients with microsatellite-stable colorectal cancer—those historically left without effective options,” said Dr. Chris O’Callaghan, DVM, PhD, Senior Investigator, Canadian Cancer Trials Group. “Earlier CCTG studies suggested that doublet immunotherapy could extend survival even in cold tumors, and the magnitude and durability of responses seen with botensilimab and balstilimab in earlier studies warrant their investigation in a phase 3 trial.”

“The enthusiasm among investigators has been remarkable—within days of Health Canada submission, leading centers across Canada moved to open the study. We’re eager to advance this global effort and potentially transform outcomes for patients who have exhausted all other treatments,” said Dr. Jonathan Loree, MD, MSc, FRCPC, CO.33 Study Chair.

About the BATTMAN (CO.33) Trial

The BATTMAN (CCTG CO.33) (NCT07152821) trial is a global Phase 3, randomized, controlled study evaluating botensilimab (BOT) plus balstilimab (BAL) versus best supportive care in patients with refractory, unresectable microsatellite stable (MSS)/mismatch repair proficient (pMMR) colorectal cancer. Conducted as an international cooperative group study led by the Canadian Cancer Trials Group (CCTG), the trial will enroll approximately 830 patients across more than 100 sites in Canada, France, Australia, and New Zealand. Participating academic networks include CCTG, the GI Cancer Trials, and France’s Partenariat de Recherche en Oncologie Digestive (PRODIGE), sponsored by UNICANCER. This registrational-enabling study is designed to support potential regulatory submissions for BOT+BAL in this difficult-to-treat patient population. Patients interested in learning more about the study, including eligibility and enrollment information, can visit: <https://www.ctg.queensu.ca/patients/colorectal-cancer-clinical-trial-co33>.

About Agenus

Agenus is a leading immuno-oncology company targeting cancer with a comprehensive pipeline of immunological agents. The company was founded in 1994 with a mission to expand patient populations benefiting from cancer immunotherapy through combination approaches, using a broad repertoire of antibody therapeutics, adoptive cell therapies (through MiNK Therapeutics) and adjuvants. Agenus has robust end-to-end development capabilities,

across commercial and clinical cGMP manufacturing facilities, research and discovery, and a global clinical operations footprint. Agenus is headquartered in Lexington, MA. For more information, visit www.agenusbio.com or @agenus_bio. Information that may be important to investors will be routinely posted on our website and social media channels.

About Canadian Cancer Trials Group (CCTG)

The Canadian Cancer Trials Group (CCTG) is a cancer clinical trials research cooperative that runs phase I-III trials to test anti-cancer and supportive therapies across Canada, and internationally. Headquartered at Queen's University, CCTG has supported more than 700 trials enrolling 100,000 patients from 40 countries on 6 continents through a global network of 20,000 investigators and clinical trial staff. CCTG is the Canadian Coordinating Clinical Trial Network for the US NCTN and is a national program of the Canadian Cancer Society. CCTG's aim is to improve survival and quality of life for all people with cancer. Learn more at cctg.ca.

About Botensilimab (BOT)

Botensilimab (BOT) is a human Fc enhanced multifunctional anti-CTLA-4 antibody designed to boost both innate and adaptive anti-tumor immune responses. Its novel design leverages mechanisms of action to extend immunotherapy benefits to "cold" tumors which generally respond poorly to standard of care or are refractory to conventional PD-1/CTLA-4 therapies and investigational therapies. Botensilimab augments immune responses across a wide range of tumor types by priming and activating T cells, downregulating intratumoral regulatory T cells, activating myeloid cells and inducing long-term memory responses.

Approximately 1,200 patients have been treated with botensilimab and/or balstilimab in phase 1 and phase 2 clinical trials. Botensilimab alone, or in combination with Agenus' investigational PD-1 antibody, balstilimab, has shown clinical responses across nine metastatic, late-line cancers. For more information about botensilimab trials, visit www.clinicaltrials.gov.

About Balstilimab (BAL)

Balstilimab is a novel, fully human monoclonal immunoglobulin G4 (IgG4) designed to block PD-1 (programmed cell death protein 1) from interacting with its ligands PD-L1 and PD-L2. It has been evaluated in more than 900 patients to date and has demonstrated clinical activity and a favorable tolerability profile in several tumor types.

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 regarding its botensilimab and balstilimab programs, expected regulatory timelines and filings, and any other statements containing the words "may," "believes," "expects," "anticipates," "hopes," "intends," "plans," "forecasts," "estimates," "will," "establish," "potential," "superiority," "best in class," 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 Annual Report on Form 10-K for 2024, and subsequent Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission. 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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