

Agenus Completes Enrollment in Randomized Phase 2 Clinical Trial of Botensilimab/Balstilimab in Advanced Colorectal Cancer

10/10/2023

LEXINGTON, Mass.--(BUSINESS WIRE)-- Agenus Inc. (Nasdaq: AGEN), a leader in developing novel immunological agents to treat various cancers today announced completion of the planned patient enrollment in ACTIVATE-Colorectal, a randomized Phase 2 trial in advanced colorectal cancer (CRC) evaluating the efficacy and safety of botensilimab (BOT) as monotherapy and in combination with balstilimab (BAL) or standard of care in patients with metastatic heavily pre-treated colorectal cancer.

The phase 2 study follows an expanded phase 1 study of over 100 patients with a median of four prior lines of therapy and with 25% having failed previous immunotherapy. At ESMO GI earlier this year, data from the phase 1 study were presented. Among the evaluable patients (n=69) who did not have active liver metastases, a confirmed objective response rate of 23% and a median overall survival of 20.9 months were observed.

"There is a significant need for improved treatment options for heavily pre-treated CRC patients and we anticipate data from ACTIVATE-Colorectal will build upon the positive results from our phase 1 study," said Chief Medical Officer, Dr. Steven O'Day. "Our gratitude goes out to the patients, care partners, physicians, and nurses involved in this trial, as we push forward with BOT/BAL to bridge vital gaps in cancer care."

Agenus is exploring global accelerated approval strategies for CRC. The totality of data from the phase 1 and 2 studies will contribute to a planned Biologics License Application to the U.S. FDA in 2024. The U.S. FDA has granted Fast Track designation for BOT/BAL in patients with non-MSI-H/dMMR metastatic colorectal cancer and no active liver involvement who 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.

About Botensilimab

Botensilimab is an investigational multifunctional anti-CTLA-4 immune activator 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 other 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 600 patients have been treated with botensilimab 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 with the identifiers NCT03860272, NCT05608044, NCT05630183, and NCT05529316.

Access to Investigational Medicines Policy

Agenus is committed to making our investigational therapies available to patients with cancer based upon advice of a treating physician. Physicians and patients interested in accessing the BOT/BAL combination for CRC should follow the **compassionate use policy** available on the Agenus website.

About Agenus

Agenus is a leading immuno-oncology company targeting cancer and infectious diseases with a comprehensive pipeline of immunological agents. The company's mission is 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 (through SaponiQx). Agenus is headquartered in Lexington, MA. For more information, visit www.agenusbio.com or [@agenus_bio](https://twitter.com/agenus_bio). Information that may be important to investors will be routinely posted on our website and social media channels.

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 the anticipated savings as a result of the strategic initiative, the timing of potential regulatory applications, approval and commercialization for BOT/BAL, the continued development of Agenus' partnered programs, the reactivation of certain pipeline programs, use of botensilimab and balstilimab, for instance, statements regarding therapeutic benefit and efficacy, mechanism of action (including validation of mechanism of action), potency, durability, and safety profile (including the absence of specific

toxicities); 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 Quarterly Report on Form 10-Q or Annual Report on Form 10-K 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.

Investors

917-362-1370

investor@agenusbio.com

Media

781-674-4784

communications@agenusbio.com

Source: Agenus Inc.