Balstilimab Monotherapy Data Published in Gynecologic Oncology

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- Objective response rate of 20% and median duration of response not reached with 14.6 month median follow-up in PD-L1+ tumors
- Responses seen across all histology subgroups including populations of patients unresponsive to other therapies

LEXINGTON, Mass., Aug. 26, 2021 (GLOBE NEWSWIRE) -- Agenus Inc. (NASDAQ: AGEN), an immuno-oncology company with an extensive pipeline of checkpoint antibodies, cell therapies, adjuvants, and vaccines designed to activate immune response to cancers and infections, today announced that results from a global Phase 2 clinical study of balstilimab monotherapy in recurrent/metastatic cervical cancer were published online in the international peer reviewed journal *Gynecologic Oncology* (https://doi.org/10.1016/j.ygyno.2021.08.018).

“Publication of these data marks another significant achievement toward our objective to provide effective therapeutic options to those battling cancer,” said Steven O’Day, MD, Chief Medical Officer of Agenus. “These data are drawn from the largest Phase 2 study to date evaluating PD-1 inhibition in advanced cervical cancer patients who have progressed on or after first-line chemotherapy; the results indicate balstilimab’s potential as an effective new therapy.”

In the 140 evaluable patients, the objective response rate (ORR) in patients with PD-L1 positive tumors was 20.0% and included 3 patients (3/85, 3.5%) with a complete response and 14 patients (14/85, 16.5%) with a partial response. The median duration of response (DoR) was not reached after a 14.6-month median follow-up. Responses were also observed in the PD-L1 negative population with an ORR of 7.9%. The confirmed ORR for both PD-L1 positive and negative tumors was 15.0% and included 5 patients (3.6%) with a complete response and 16 patients (11.4%) with a partial response. The median DoR was 15.4 months and the disease control rate was ~50%. Notably, responses were observed across histologies, with responses in the squamous cell histology (ORR 17.6%) and in the more difficult to treat adenocarcinoma histology (ORR 12.5%). The safety profile was manageable and consistent with that of currently approved anti-PD-1 antibodies; it also compared favorably to the safety profiles of chemotherapies used in this population. Data from this trial continue to mature.

As discussed in the publication, these data suggest that balstilimab may be a differentiated anti-PD-1 antibody as compared to currently approved PD-1 inhibitors. In the KEYNOTE-158 trial of pembrolizumab, an anti-PD-1 antibody, in the same setting, an ORR of 14.6% was observed in the PD-L1 positive population and no responses were observed in the PD-L1 negative population. In addition, the noted 12.5% response rate of balstilimab in patients with cervical adenocarcinoma is significant as this subpopulation typically does not respond to immunotherapy and represents a growing proportion of advanced cervical cancer cases. Balstilimab thus provides the potential for therapeutic benefit to patient populations that do not typically respond to currently-available immunotherapy, both alone and in combination with other therapies, such as Agenus’ anti-CTLA-4 antibodies zalifrelimab and AGEN1181. Final results from a Phase 2 trial of balstilimab in combination with zalifrelimab in advanced cervical cancer will be presented in a Mini Oral Session at the European Society for Medical Oncology (ESMO) Congress 2021 on September 19 from 11:35 – 11:40am ET by David O’Malley, MD.

“The efficacy and safety of balstilimab provides additional evidence of the importance of immune checkpoint blockade in the treatment of recurrent, advanced cervical cancer patients,” said David O’Malley, MD, Professor, Department of Obstetrics and Gynecology, The Ohio State University College of Medicine; Director, Division of Gynecologic Oncology, OSUCCC – James; and lead author on the publication. “Furthermore, responses to balstilimab were seen in patients who were PD-L1 positive, PD-L1-negative, bevacizumab pre-treated, and squamous cell and adenocarcinoma histologies. Balstilimab clearly provides clinical benefit in a broad range of cervical cancer patients.”

Study Design (NCT03104699)
This was an open-label, single-arm, global Phase 2 clinical trial conducted at 60 sites throughout the United States, Europe, South America, and Australia. Patients were enrolled from November 20, 2017, to April 16, 2020, and received intravenous balstilimab at a dose of 3 mg/kg once every two weeks, given as a 60-minute infusion. Treatment was permitted for up to 24 months, or until disease progression, intolerable toxicity, or investigator/patient decision.

About Balstilimab Monotherapy
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. PD-1 is a negative regulator of immune activation that is considered a foundational target within the immuno-oncology market. Agenus announced it had submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) on April 19, 2021, for use in patients with recurrent or metastatic cervical cancer, and the application is under priority review with a target action date of December 16, 2021.

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. 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 MiNK Therapeutics subsidiary), adjuvants, and proprietary cancer vaccine platforms. 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 regarding potential therapeutic benefit and future clinical development plans for balstilimab, zalifrelimab, and AGEN1181 alone and in combination with other agents. 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.

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