# Agenus Submits Balstilimab Biologics License Application to the U.S. FDA for Patients with Recurrent or Metastatic Cervical Cancer

April 19, 2021

- Submission has been made for review under the accelerated approval pathway

LEXINGTON, Mass., April 19, 2021 (GLOBE NEWSWIRE) -- Agenus Inc. (NASDAQ: AGEN), an immuno-oncology company with an extensive pipeline of agents which includes checkpoint antibodies, cell therapies, adjuvants, and vaccines designed to activate immune response to cancers and infections, today announced the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA). The BLA has been submitted for the accelerated approval of balstilimab, Agenus' anti-PD-1 antibody, for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy, and includes data from its pivotal Phase 2 single-arm clinical trial, presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020. These clinical data, along with preclinical data, suggest that balstilimab demonstrates differentiated features from other anti-PD-1 antibodies.

"Women with recurrent or metastatic cervical cancer have a very poor prognosis and limited treatment options. Data suggest balstilimab may bring benefit to patients beyond what is available in this disease setting today," said Jennifer Buell, PhD, President and Chief Operating Officer at Agenus. "This submission also marks a significant step in our transition to a commercial company and the advancement of our oncology combination strategy."

The balstilimab BLA submission is based on an update to data presented at the ESMO Virtual Congress 2020 and published in an *Oncogene* editorial, which demonstrate that balstilimab shows potential differentiation from other anti-PD-1 antibodies. This updated dataset includes maturation of late patient responses, with the overall data showing response rates of 20% in PD-L1 positive tumors, 15% in all tumors (PD-L1 positive and negative), and a median duration of response of 15.4 months.

"We expect that the potential approval of balstilimab will enable us to better pursue our oncology combination strategy for our own extensive pipeline of agents as well as for existing and future partner products," said Steven O'Day, MD, Chief Medical Officer at Agenus. "In particular, we hope to use this potential approval to allow us to rapidly proceed with our anti-CTLA-4 combination strategy, which we believe can add significantly to the benefit provided by our anti-PD-1 agent. There are currently limited treatment options available for recurrent or metastatic cervical cancer patients, and our vision is to bring effective treatments to these patients."

In April 2020, the FDA granted Fast Track designation for balstilimab in recurrent or metastatic cervical cancer based on its potential to provide benefit to patients with a serious condition and unmet medical need.

A global, randomized, Phase 3 confirmatory clinical trial designed to support global registration is planned.

**About Cervical Cancer**

Nearly 14,000 women are expected to be diagnosed with invasive cervical cancer in the United States this year and more than 4,000 are expected to die. Cervical cancer remains one of the leading causes of cancer death in women globally, annually killing more than 300,000 women worldwide.[1] Despite advances in routine medical examinations and HPV vaccines, cervical cancer remains prevalent. When left undetected, recurrent or metastatic cervical cancer often develops, for which there are limited treatment options and a low chance of survival. Current therapies for recurrent or metastatic cervical cancer are limited to a small subset of patients with limited benefit.

**About balstilimab**

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. Balstilimab is currently in clinical trials as monotherapy and in combination with Agenus' anti-CTLA-4, zalifrelimab, in an ongoing Phase 2 study for recurrent/metastatic cervical cancer.

**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 AgenTus Therapeutics subsidiary), 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 future clinical trials, potential clinical benefit of our products, and future product development plans for balstilimab 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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1 https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21660