Agenus Announces U.S. FDA Acceptance and Priority Review of Balstilimab Biologics License Application for the Treatment of Recurrent or Metastatic Cervical Cancer

June 17, 2021

LEXINGTON, Mass., June 17, 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 that the U.S. Food and Drug Administration (FDA) has accepted Agenus' Biologics License Application (BLA) for balstilimab, an anti-PD-1 antibody, for the treatment of recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. The FDA has granted Priority Review to this submission, a designation for drugs which, if approved, may provide significant improvements in the safety or effectiveness of the treatment of serious conditions. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of December 16, 2021.

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.[1] Cervical cancer remains one of the leading causes of cancer death in women globally, annually killing more than 300,000 women worldwide.[2] 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.

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[1] https://www.cancer.org/cancer/cervical-cancer/about/key-statistics.html

[2] https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21660