Agenus Presents New Data on Balstilimab and AGEN2373 in ASCO Abstracts

May 20, 2021

LEXINGTON, Mass., May 20, 2021 (GLOBE NEWSWIRE) -- Agenus (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 data on the differentiated activity profile of balstilimab, an anti-PD-1 antibody, and new Phase 1 clinical data for AGEN2373, a CD137 agonist antibody, as published in abstracts for two posters to be presented at the American Society for Clinical Oncology (ASCO) Annual Meeting 2021 from June 4 – 8, 2021.

Balstilimab has shown expanded clinical activity in a Phase 2 clinical trial for patients with recurrent or metastatic cervical cancer. Responses have been observed in both PD-L1 positive and PD-L1 negative tumors in contrast to approved anti-PD-1 antibodies which have shown almost no responses in the PD-L1 negative population. Preclinical observations using the company's proprietary platform corroborate these results, showing differentiated activity and superior tumor killing potential for balstilimab as compared to commercially available anti-PD-1 antibodies.

Agenus submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) on April 19 for the use of balstilimab in patients with recurrent or metastatic cervical cancer. This submission was based on data from the Phase 2 trial showing a response rate of 20% in PD-L1 positive tumors and an overall response rate of 15% with a median duration of response of 15.4 months.

AGEN2373 is a conditionally active CD137 agonist antibody designed to overcome limitations seen with first-generation CD137 agonist antibodies, including the development of liver toxicity. In this first-in-human study of AGEN2373 in patients with advanced solid tumors, no dose limiting toxicities were seen at doses up to 3 mg/kg; notably, no liver toxicity has been observed. Five patients demonstrated stable disease out of 19 patients treated with AGEN2373 monotherapy, including one heavily pretreated patient with metastatic leiomyosarcoma who had progressed on prior combination checkpoint immunotherapy.

"We are encouraged by the differentiated qualities of our anti-PD-1 balstilimab both in the clinic and in preclinical models," said Steven O'Day, MD, Chief Medical Officer at Agenus. "Our novel CD137, AGEN2373, has been well tolerated in this dose escalation trial and we look forward to advancing it into combinations for potential benefit to patients."

Presentation Details:

Abstract title: Differentiated activity profile for the PD-1 inhibitor balstilimab
Abstract number: 5529
Poster Session: Gynecologic Cancer
Presenting author: Cailin Joyce, PhD

Abstract title: Initial findings of the first-in-human Phase I study of AGEN2373, a conditionally active CD137 agonist antibody, in patients (pts) with advanced solid tumors
Abstract number: 2634
Poster Session: Developmental Therapeutics—Immunotherapy
Presenting author: Anthony Tolcher, MD

The 2021 ASCO Annual Meeting will take place on June 4 – 8, 2021.

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.

A Biologics License Application has been submitted to the U.S. Food and Drug Administration for the use of balstilimab to treat recurrent/metastatic cervical cancer.

About AGEN2373
AGEN2373 is a novel, fully human monoclonal conditionally active CD137 agonist antibody designed to selectively enhance CD137 co-stimulatory signaling in activated immune cells while mitigating side effects associated with systemic activation of CD137. CD137 (4-1BB) is a positive regulator of the immune system that is highly upregulated on activated T cells (adaptive immune cells) and NK cells (innate immune cells).

AGEN2373 is advancing in a Phase 1 clinical trial against solid tumors.

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 development plans for AGEN2373 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.

Contact

Agenus Investor Relations
Jan Medina, CFA
Agenus
781-674-4490
Jan.Medina@agenusbio.com

Agenus Media Relations
Kimberly Ha
KKH Advisors
917-291-5744
kimberly.ha@kkhadvisors.com