Agenus' Presentations at ASCO 2021 Demonstrate Differentiated Activity of Balstilimab and Provide Clinical Update on AGEN2373

June 4, 2021

LEXINGTON, Mass., June 04, 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 presented data demonstrating the differentiation of balstilimab as an anti-PD-1 antibody as well as data from a Phase 1 clinical trial of AGEN2373, a CD137 agonist antibody, at the American Society of Clinical Oncology (ASCO) Annual Meeting 2021 from June 4 – 8, 2021.

Agenus submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) on April 19, 2021 for the use of balstilimab in patients with recurrent or metastatic cervical cancer. This submission was based on data from a Phase 2 trial in patients with recurrent or metastatic cervical cancer. These data show 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. Balstilimab shows responses across histology subgroups and in populations of patients typically unresponsive to commercially available therapies, such as patients with PD-L1 negative tumors.

Preclinical studies using Agenus' proprietary R&D VISION platform underscored these observed clinical data. VISION demonstrates that balstilimab may be superior to currently approved anti-PD-1 antibodies such as pembrolizumab and nivolumab. Balstilimab showed superior tumor killing in both PD-L1 positive and PD-L1 negative tumors compared to commercially available anti-PD-1 antibodies in these studies.

"We are encouraged by the initial performance of our VISION platform both for drug discovery and potential therapeutic predictive modeling. It has the potential to bring effective treatments to patients more rapidly," said Steven O'Day, MD, Chief Medical Officer of Agenus. "AGEN2373 continues to show no liver toxicity in the clinic, and we expect the anticipated combination trials to provide potential benefit to patients."

AGEN2373 is a CD137 agonist antibody designed to overcome limitations seen with first-generation CD137 agonist antibodies, particularly 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 well above the threshold at which liver toxicity is usually seen with other CD-137 agonist antibodies. Five patients demonstrated stable disease out of 22 patients treated with AGEN2373 monotherapy, with prolonged stable disease observed in three of these patients. AGEN2373 is expected to provide benefit especially in combination therapy, and combination trials are in planning.

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

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 currently in a Phase 1 clinical trial against solid tumors.

About VISION
VISION (**VI**rtual **S**ystems for **I**mmuno-**ON**cology) is an active learning platform that mimics a patient's tumor microenvironment and immune system in order to define predictive biomarker signatures. VISION leverages advanced analytics to explore an immense range of drug-biology interactions not possible via traditional processes. Producing informative data feedback loops in real-time, VISION enables quicker validation of drug targets, faster optimized molecule design and drug candidate selection, and personalized treatment regimens based on biomarker signatures.

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 potential therapeutic benefit and future clinical development plans for balstilimab and 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