Agenus Commences Phase 1 trial with AGEN1223

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- AGEN1223 is a novel bi-specific designed to selectively deplete regulatory T cells in the tumor microenvironment

- First patient dosed; combinations with other IO agents planned for 2020

LEXINGTON, Mass., Jan. 8, 2020 /PRNewswire/ -- Agenus Inc. (NASDAQ: AGEN), an immuno-oncology company with an extensive pipeline of agents that activate immune response to cancers, announced the dosing of the first patient with AGEN1223. AGEN1223 is a novel bi-specific antibody discovered by Agenus and designed to deplete regulatory T cells in the tumor microenvironment. The first patient was infused in December 2019 and the trial is underway with a plan to initiate combinations with balstilimab, Agenus' investigational PD-1 inhibitor, in 2020.

Dr. Anthony El-Khoueiry of the USC Norris Comprehensive Cancer Center and Keck School of Medicine was the clinical investigator dosing this first patient. Dr. El-Khoueiry is the phase I program director and a recognized expert in early drug development and translational medicine with a focus in hepatobiliary (liver, gall bladder, and bile duct) and pancreatic cancers.

"AGEN1223 is a novel bispecific antibody designed to selectively deplete specific immune-suppressive cells called regulatory T cells. The ability to deplete these cells in the tumor microenvironment may be an important treatment advantage for patients with cancer," said Dr. Anna Wijatyk, Head of Clinical Development at Agenus. "AGEN1223 is designed to eliminate the escape pathways that tumors use to continue to grow beyond multiple lines of therapy, including anti-PD-1 therapy. We believe that AGEN1223, due to its design to both selectively deplete intratumoral Tregs while sparing peripheral Tregs and to activate effector immune cells, represents an important novel therapy and promising combination agent for patients with aggressive tumors."

The Phase 1, open-label, multicenter study is designed to assess the maximum tolerated dose of AGEN1223 in subjects with advanced solid tumors. It will also evaluate the safety, tolerability, PK, and PD profiles and immunogenicity of this bi-specific antibody.

AGEN1223 was discovered by Agenus scientists and engineered to enhance immune functionality and immunogenicity. Our preclinical data show that AGEN1223 simultaneously engages two antigens that are co-expressed specifically on tumor-infiltrating Tregs thereby prompting their depletion. These data further show that cancer-fighting effector T cells and essential peripheral Tregs, which do not sufficiently co-express these targets, are largely spared from destruction. In addition to its Treg depleting capabilities, AGEN1223 can co-stimulate antigen-specific effector T cells that are essential for tumor killing in preclinical assays. Overall, AGEN1223 may represent a promising combination partner for a range of other therapeutic interventions – which could include checkpoint inhibitors, vaccines, or cell therapy. Gilead Sciences, Inc. has an exclusive option to license AGEN1223 as part of our December 2018 collaboration agreement with the company. Agenus is currently responsible for the development of AGEN1223. AGEN1223 and balstilimab are investigational agents. Their safety and efficacy are being evaluated in a Phase 1 clinical trial.

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, proprietary cancer vaccine platforms, and adoptive cell therapies (through its AgenTus Therapeutics subsidiary). 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 early phase 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: the clinical utility of AGEN1223; expectations regarding the results of the Phase 1 study of AGEN1223; expectations for future clinical trial plans and development activities of AGEN1223; our clinical trial plans and activities, research and development plan and activities for antibodies other than AGEN1223; and the anticipated operations and benefits of AGEN1223 and our other programs. 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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