Agenus Commences Combination Trial of its Next-Gen CTLA-4 with its PD-1 Antibody

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LEXINGTON, Mass., Dec. 19, 2019 /PRNewswire/ -- Agenus Inc. (NASDAQ: AGEN), an immuno-oncology (I-O) company with a pipeline of immune checkpoint antibodies, adoptive cell therapies[1] and cancer vaccines, today announced the first patient dosed with AGEN1181, an anti-CTLA-4 antibody, in combination with balstilimab, Agenus' PD-1 inhibitor. Agenus began this study as a monotherapy in patients with advanced solid tumors within a Phase 1 dose escalation study (NCT03860272) in April 2019.

The first patients to be treated with AGEN1181 as a monotherapy as well as the combination trial with PD-1 were dosed by Dr. Steven O'Day, Executive Director of the John Wayne Cancer Institute & Cancer Clinic, and a pioneer in delivering immune therapies to patients with cancer.

"AGEN1181, with its potential for enhanced immune activation and tumor fighting abilities, may bring superior benefit to a broader group of patients compared to first generation anti-CTLA-4 antibodies," said Dr. O'Day. "The pre-clinical data suggest the superiority of this molecule as a monotherapy and in combination with anti-PD-1, like balstilimab. Furthermore, AGEN1181 was designed to bring benefit to a broad population of patients both who respond to first generation molecules and those who do not respond due to a genetic polymorphism. Expanding the important immune priming benefit of CTLA-4 to a broad group of patients would be outstanding. I am thrilled to be working with this compound."

Balstilimab, the company's proprietary anti-PD-1 antibody, is currently being evaluated as a monotherapy and in combination with zalfrelimab (a first generation CTLA-4) in trials designed to support a planned BLA filing in 2020 for patients with relapsed/refractory cervical cancer.

This expanded trial is another example of Agenus' ability to rapidly advance its novel pipeline. Next-Gen CTLA-4 is a novel antibody from Agenus' discovery engine, and with its own PD-1 molecule, Agenus has been able to move this important combination into the clinic with a high sense of urgency.

About AGEN1181
AGEN1181, a novel 'Fc engineered' antibody with potential for enhanced anti-tumor functions, is specifically designed to boost cancer killing immune cells and deplete intratumoral regulatory T cells that promote immune evasion. By enhancing binding to a specific Fc receptor, FcγRIIIA, on antigen-presenting cells or natural killer cells, AGEN1181 significantly enhances the therapeutic potential of anti-CTLA-4 therapy leveraging novel mechanisms that are not captured by the first-generation anti-CTLA-4 therapies. AGEN1181's Fc engineered backbone improves the cross-talk between antigen-presenting cells and T cells, to enable optimal T cell priming, activation and formation of durable memory responses. Moreover, AGEN1181 enhanced binding to FcγRIIIA, significantly increases the potential to deplete intratumoral regulatory T cells, a significant barrier to successful anti-cancer immune responses. Notably, AGEN1181 is engineered to strongly bind both the low affinity and high affinity FcγRIIIA polymorphisms, unlike first generation molecules which weakly bind the low affinity polymorphism. AGEN1181 is designed to expand the benefit to an additional ~40% of patients with the low affinity polymorphism and enhance the benefits of CTLA-4 in all patients.

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 with combination approaches that leverage a broad repertoire of antibody therapeutics, adoptive cell therapies (through its AgenTus Therapeutics subsidiary) and its proprietary cancer vaccine platforms. Agenus has 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 Agenus' clinical development and regulatory plans and timelines and the potential therapeutic benefit of AGEN1181. 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]Through AgenTus Therapeutics, a subsidiary of Agenus

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