Completion of Balstilimab BLA Filing Extended To 1H2021

December 3, 2020

Agenus to fulfill FDA feedback for six-month follow-up on late responders

LEXINGTON, Mass., Dec. 03, 2020 (GLOBE NEWSWIRE) -- Agenus Inc. (NASDAQ: AGEN), an immuno-oncology company with a broad pipeline which includes checkpoint antibodies, cell therapies, adjuvants, and vaccines designed to activate immune response to cancers and infections, today announced updated timing of the balstilimab BLA filing to meet the FDA feedback to follow all patients for a median of 12 months and responders for a minimum of 6 months. Due to two newly-identified late responses in the trial, the completion of the BLA filing is planned for the first half of 2021. In parallel, Agenus is working with the FDA to clarify diagnostic requirements for PD-L1 testing.

The additional follow-up is required to present data on two patients who experienced durable disease stabilization and converted to confirmed responses on long-term balstilimab therapy.

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 regulatory timelines for the BLA filings of balstilimab alone and in combination with zalifrelimab. 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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