Agenus Receives Fast Track Designation for Balstilimab & Zalifrelimab in Advanced Cervical Cancer

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LEXINGTON, Mass., March 12, 2020 /PRNewswire/ -- Agenus Inc. (NASDAQ: AGEN), an immuno-oncology company with an extensive pipeline of agents designed to activate immune response to cancers, today announced that the U.S. Food and Drug Administration (FDA) has granted Agenus Fast Track designation for investigation of balstilimab [PD-1] in combination with zalifrelimab [CTLA-4] for the treatment of patients with relapsed or refractory metastatic cervical cancer. This designation was based on comprehensive data that support the potential for balstilimab and zalifrelimab to address a significant unmet medical need. Agenus expects to file 2 BLAs this year for accelerated approval of the combination of balstilimab and zalifrelimab and balstilimab monotherapy in metastatic cervical cancer.

Agenus Logo

"We are pleased that balstilimab and zalifrelimab have been granted Fast Track designation by FDA in recognition of the high unmet medical need in second line cervical cancer. The Fast Track designation confers important benefits, including the potential eligibility for a Priority Review," said Dr. Jennifer Buell, President and COO, Agenus. "We are excited about the prospect of making these novel agents available to women who suffer from metastatic cervical cancer. We look forward to continuing to work with FDA as we advance new treatment options for patients with cancer."

Agenus has reported updated data from a pre-planned interim analysis revealing robust and durable activity of balstilimab and zalifrelimab in patients with relapsed or refractory metastatic cervical cancer. The data demonstrated 26.5% objective response rates (ORR) (4 CRs, 5 PRs, 8 SD) which are durable (median not yet reached) in an all-comer, non-biomarker selected population of patients with refractory cervical cancer who have failed prior platinum chemotherapy with or without bevacizumab.

Fast Track designation is granted by the FDA for products that are intended for the treatment of serious or life-threatening disease or conditions, which demonstrate the potential to address an unmet medical need. The designation offers the opportunity for frequent interactions with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval, as well as eligibility for rolling submission of a Biologic Licensing Application (BLA).

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 Agenus' anticipated BLA filings and the anticipated benefits of Fast Track designation. 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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