Agenus Initiates Rolling BLA Submission of Balstilimab for Recurrent/Metastatic Cervical Cancer

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LEXINGTON, Mass., Sept. 18, 2020 (GLOBE NEWSWIRE) -- Agenus Inc. (NASDAQ: AGEN), an immuno-oncology company with an extensive pipeline of checkpoint antibodies, cell therapy, adjuvants, and vaccines designed to activate immune response to cancers and infections, announced the initiation of the rolling submission of its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for balstilimab alone for the treatment of recurrent/metastatic cervical cancer.

Data from the largest phase 2 trial of anti-PD-1 in patients with refractory cervical cancer was presented today at the European Society for Medical Oncology (ESMO) Virtual Congress https://agenusbio.com/balstilimab-balstilimab-zalifrelimab/. Data from more than 160 patients treated with balstilimab (anti-PD-1) monotherapy achieved response rates of 19% in PD-L1 positive patients and 14% in all treated patients and will support the balstilimab BLA filing.

Balstilimab is a novel anti-PD-1 human monoclonal antibody that has demonstrated promising clinical benefit in second line treatment of cervical cancer.

“The initiation of the rolling BLA is an exciting step forward for Agenus as we are closer to making our therapies commercially available for patients with cervical cancer who have limited treatment options available,” said Dr. Jennifer Buell, President and COO of Agenus. “We continue to collaborate with the leading KOLs and the FDA in our efforts to make these treatments available to patients.”

A rolling submission allows Agenus to submit each section of the BLA as it is completed, which enables the FDA to review the submitted sections in parallel with Agenus’s completion of the balance of the BLA application.

The American Cancer Society estimates around 14,000 new cases of invasive cervical cancer to be diagnosed this year and nearly 4,300 cervical cancer deaths. This population needs new therapies that safely provide clinical benefit across 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 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 clinical development and regulatory plans and timelines. 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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