Combination of Balstilimab Plus Zalifrelimab Doubles Responses in 2L Cervical Cancer in Data to Be Presented at ESMO

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- Objective response rate of 33% and median duration of response not reached with 19.4 months median follow-up in PD-L1+ tumors; expands benefit of anti-PD-1 alone
- Improved responses seen across all histology subgroups including populations of patients unresponsive to other therapies
- Dr. David O'Malley to present data in an oral presentation on Sept. 19 th

LEXINGTON, Mass., Sept. 16, 2021 (GLOBE NEWSWIRE) -- Agenus (NASDAQ: AGEN), an immuno-oncology company with an extensive pipeline of checkpoint antibodies, cell therapies, adjuvants, and vaccines designed to activate immune response to cancers and infections, today presented final results from the Bal/Zal combination study at the European Society for Medical Oncology (ESMO) Virtual Conference 2021 in an abstract titled *Balstilimab (anti-PD-1) in combination with zalifrelimab (anti-CTLA-4): final results from a Phase 2 study in patients (pts) with recurrent/metastatic (R/M) cervical cancer (CC).*

The data are being presented by lead investigator Dr. David O'Malley, Professor of Obstetrics and Gynecology at The Ohio State University College of Medicine and the Director of the Division of Gynecologic Oncology, The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute (OSUCCC – James).

"With a median follow-up of almost 2 years, the Bal/Zal combination showed high response rates, durable clinical activity, and promising overall survival results", said Steven O'Day, MD, Chief Medical Officer of Agenus. "Furthermore, later this year we expect to present new data on our next-generation CTLA-4 inhibitor AGEN1181, which we expect to further define the positive role this combination strategy could have in addressing unmet needs for cancer patients."

The Phase 2 trial was conducted in 155 patients with recurrent/metastatic cervical cancer (R/M CC) which has limited effective treatment options and disproportionately affects younger women. In the 125 evaluable patients, the objective response rate (ORR) in all patients was 26%, with 9% of patients achieving a complete response, and 17% of patients achieving a partial response. The median duration of response (DoR) was not reached after a 19.4-month median follow-up. Notably, responses were also observed in the PD-L1 negative and adenocarcinoma populations, with 9% of both patient groups achieving an ORR. Based on these observations, we predict more than half of the patients to be alive beyond 12 months*.

The Bal/Zal combination continued to show no unexpected toxicities and no new safety signals were identified.

Detailed results from this trial will be presented in a Mini Oral Session on September 19th from 11:35 – 11:40am ET by David O'Malley, MD. In addition, in a Trials in Progress abstract, Agenus presented the RaPiDS trial design for balstilimab alone or in combination with zalifrelimab as second-line treatment for patients with previously treated R/M CC.

"This trial represents the largest study evaluating PD-1 + CTLA-4 inhibition in relapsed cervical cancer to date and shows that the combination could represent a meaningful new option for patients in this setting," said Dr. O'Malley. "Efficacy outcomes continued to improve over time, and the combination likewise continued to show a positive safety profile."

** Updated data to be presented during September 19th Mini Oral session.*

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 MiNK Therapeutics subsidiary), adjuvants, 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 potential therapeutic benefit and future clinical development plans for balstilimab, zalifrelimab, and AGEN1181 alone and in combination with other agents. 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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