Agenus Presents Results from Two Large Cervical Cancer Trials at ESMO

September 18, 2020

- 160 patient balstilimab (PD-1) monotherapy trial achieves response rates of 14% in all treated patients and 19% in PD-L1 positive patients
- 155 patient balstilimab (PD-1) + zalifrelimab (CTLA-4) combination trial achieves response rates of 22% in all patients and 27% in PD-L1 positive patients

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, today presented preliminary results from two large clinical trials of more than 150 patients each at the European Society for Medical Oncology (ESMO) Virtual Congress 2020. Both trials were conducted in patients with recurrent/metastatic cervical cancer which has limited effective treatment options and disproportionately affects younger women.

“Balstilimab has shown activity in both PD-L1 positive and negative tumors, suggesting that we may have a potentially differentiated PD-1,” said Dr. Garo Armen, Chairman and CEO of Agenus. “Furthermore, we have also shown important expansion in response rates, to near doubling in PD-L1 positive patients, and durability of response when patients receive zalifrelimab in combination with balstilimab.”

The presentation was made by 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). Dr. O’Malley is the lead investigator of the trials presented.

“These trials represent the largest trials of immuno-oncology therapies in relapsed cervical cancer to date and show that balstilimab and zalifrelimab may present meaningful new therapies for patients with cervical cancer,” said Dr. O’Malley. “Advances in these agents offer renewed hope for patients who have limited treatment options.”

Summary of Data Presented at ESMO2020

	AGEN PD-1 Balstilimab n=160*	**AGEN PD-1 + CTLA-4 Balstilimab + Zalifrelimab** n=143*
Response rates (ORR)	**14%**	**22%**
PD-L1(+)	19%	27%
PD-L1(-)	10%	11%
ORR by tumor histology		
Squamous cell carcinoma	18%	27%
Median duration of response (months)	15.4 months	Not Reached

* mITT population; data cut-off: July 31, 2020

Agenus Presentation at ESMO Virtual Congress 2020:

Balstilimab (anti-PD-1) Alone and in Combination with Zalifrelimab (anti-CTLA-4) for Recurrent/Metastatic (R/M) Cervical Cancer (CC). Preliminary Results of Two Independent Ph2 Trials

Author: O’Malley
Session: Mini Oral - Gynecological cancers 2
Session Time: Friday, September 18 at 9:00 am CEST

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 the anticipated benefits of balstilimab and zalifrelimab based on preliminary results. 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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