



Agenus Announces New Responses for AGEN1181

February 9, 2021

- 6 total confirmed objective clinical responses in colon, ovarian, and endometrial cancers
- No complement-mediated toxicities reported

LEXINGTON, Mass., Feb. 09, 2021 (GLOBE NEWSWIRE) -- Agenus Inc. (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 announced additional confirmed objective clinical responses from its Phase 1/2 trial of AGEN1181, its next-generation anti-CTLA-4, as monotherapy and in combination with Agenus' anti-PD-1 balstilimab.

"These are very exciting results which demonstrate the potential of AGEN1181 as an efficacious next-generation CTLA-4 antibody. AGEN1181 is showing activity in difficult-to-treat tumors without the neuroendocrine or significant liver toxicities commonly observed with the currently-approved CTLA-4 antibody ipilimumab," said Dr. Steven O'Day, Chief Medical Officer at Agenus. "The responses seen in patients with ovarian and MSS colorectal cancer are particularly encouraging given the generally low activity seen with immunotherapy in these indications."

The Phase 1 dose escalation trial has had no reports of complement-mediated toxicities. These are severe toxicities associated with first-generation CTLA-4 antibodies. The trial has also defined the optimal combination dose for AGEN1181 +/- balstilimab.

Agenus also presented on the first-ever report of intratumoral Treg depletion with a CTLA-4 antibody in clinical trials at SITC 2020.

The summary of responses with AGEN1181 alone or in combination with balstilimab are as follows:¹

- **CR** in PD-L1(-) MSS endometrial cancer patient (1181 monotherapy)
- **CR** by PET in PD-L1(-) MSS endometrial cancer patient (1181 + bal)
- **PR** in PD-L1(-) refractory ovarian cancer patient (1181 + bal)
- **PR** in colorectal cancer patient (1181 + bal)
- **PR** in MSS colorectal cancer patient (1181 + bal) – new confirmed response
- **PR** in ovarian cancer patient (1181 + bal) – new confirmed response

AGEN1181 alone and in combination with balstilimab has expanded dosing into colorectal cancer. Phase 2 trials in additional cancer indications are scheduled to commence shortly.

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 therapeutic potential of AGEN1181 as an efficacious next-generation CTLA-4 antibody and the planned initiation of Phase 2 trials in additional cancer indications. 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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¹ Response evaluation criteria in solid tumors (RECIST v1.1)