Agenus Announces Commencement of Phase 1/2 Clinical Trial of anti-GITR Checkpoint Antibody INCAGN1876 in Patients with Solid Tumors

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LEXINGTON, Mass.--(BUSINESS WIRE)--Agenus Inc. (NASDAQ: AGEN), an immuno-oncology company developing antibodies including checkpoint inhibitors and other checkpoint modulators, and cancer vaccines, today announced that the first patient has been dosed in a Phase 1/2 clinical trial of the anti-GITR agonist antibody INCAGN1876. The trial is being conducted by, and in collaboration with, Incyte Corporation.

The open-label, dose-escalation portion of the trial will evaluate the safety and tolerability of INCAGN1876 in patients with advanced or metastatic solid tumors and determine the pharmacologically active and/or maximum tolerated dose of INCAGN1876. Part 2 of the trial is planned to further evaluate the recommended dose of INCAGN1876 in selected tumor types, including advanced or metastatic endometrial adenocarcinoma, melanoma, non-small cell lung cancer and renal cell carcinoma.

“This is the second product candidate from our antibody program that has advanced into clinical trials this year,” said Garo H. Armen, Ph.D. Chairman and CEO of Agenus. “We expect to initiate additional clinical studies with antibodies as well as other immuno-oncology leads from our comprehensive pipeline in the next twelve months.”

INCAGN1876 is an agonist antibody targeting the glucocorticoid-induced TNFR-related protein, or GITR. Upon activation, GITR, a co-stimulatory receptor, can stimulate immune cells to target and potentially destroy cancer cells. This antibody was discovered during an earlier collaboration with Ludwig Cancer Research. INCAGN1876 is being co-developed with Incyte.

“Targeted immunomodulatory therapy including anti-PD-1 and CTLA-4 drugs have demonstrated unprecedented results in cancer, but there remains significant need to improve treatment in cancer patients,” said Robert B. Stein, M.D., Ph.D., Agenus’ President, Research & Development. “GITR is a unique co-stimulatory receptor which holds great promise as a new pathway for stimulating immune cells to target cancer and may be effective alone or in combination with other immuno-modulatory approaches.”

Additional information about the trial can be found here.

About Checkpoint Antibodies

Promising clinical data from trials employing monoclonal antibodies that bind to checkpoint molecules, such as CTLA-4 and programmed death receptor-1 (PD-1), have generated considerable excitement in the field of cancer immunotherapy. These molecules serve as checks employed by the body to prevent a runaway immune response or allow rapid activation of the immune response when needed. Unfortunately, these necessary mechanisms of control can hinder the anti-cancer immune response. They can be harnessed by cancer cells as a defense against immune attack. Agenus is developing a broad pipeline of antibodies that bind to key checkpoint proteins and activate or block their activities for use in cancer therapy.

About Agenus

Agenus is an immuno-oncology company focused on the discovery and development of revolutionary new treatments that engage the body’s immune system to benefit patients suffering from cancer. By combining multiple powerful platforms, Agenus has established a highly integrated approach to target identification and validation, and for the discovery, development and manufacture of monoclonal antibodies that modulate targets of interest. The Company’s broad portfolio of novel checkpoint and other immuno-modulatory monoclonal antibodies, vaccines and adjuvants, work in combination to provide the opportunity to create best-in-class therapeutic regimens. Agenus’ heat shock protein-based vaccine, Prophage™, has successfully completed Phase 2 trials in newly-diagnosed glioblastoma. The Company has formed collaborations with Merck and Incyte to discover and develop multiple checkpoint antibodies. For more information, please visit www.agenusbio.com; information that may be important to investors will be routinely posted on our website.

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 Company’s product candidates and clinical trial plans. 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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