Agenus Announces Commencement of Phase 1/2 Clinical Trial of anti-OX40 Checkpoint Antibody INCAGN1949 in Patients with Solid Tumors

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- Third antibody from Agenus to enter the clinic this year -

LEXINGTON, Mass., Nov. 30, 2016 /PRNewswire/ -- Agenus Inc. (NASDAQ: AGEN), an immuno-oncology company with a pipeline of immune checkpoint antibodies and cancer vaccines, today announced that the first patient has been dosed in a Phase 1/2 clinical trial of the anti-OX40 agonist antibody INCAGN1949. 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 INCAGN1949 in patients with advanced or metastatic solid tumors and determine its pharmacologically active and/or maximum tolerated dose. Part 2 of the trial is planned to evaluate the recommended dose of INCAGN1949 in multiple tumor types.

"We are pleased with the progress of our fruitful alliance with Incyte and also anticipate advancing a number of Agenus programs outside of the Incyte collaboration, such as our PD-1 antagonist, AGEN2034, into clinical development in the coming months," said Garo H. Armen, Ph.D. Chairman and CEO of Agenus. "Our pipeline of proprietary and differentiated assets continues to offer opportunities for additional partnerships."

INCAGN1949 is an agonist antibody targeting OX40, otherwise known as CD134 or TNFRSF4. OX40 is a co-stimulatory receptor found on activated T cells. OX40 engagement has a two-pronged effect; it can stimulate proliferation of activated T cells that may promote tumor killing and inhibit the activity of regulatory T cells that mediate immune suppression. INCAGN1949 was discovered during an earlier collaboration with Ludwig Cancer Research. This antibody is being co-developed with Incyte.

"Immune checkpoint antibodies including those targeting PD-1/PD-L1 and CTLA-4 have shown clinical activity across multiple tumor types that supported their approval in a number of indications, but a significant proportion of patients are still in need of additional intervention," said Jean-Marie Cuillerot, M.D., VP and Global Head of Clinical Development. "OX40 is an important co-stimulatory checkpoint that contributes to the regulation of the immune anti-tumor response. We believe OX40 agonism provides a robust framework for combination therapy with a potential to make a meaningful difference to patients afflicted by this deadly disease."

Additional information about the trial can be found here.

About Checkpoint Antibodies

Monoclonal antibodies that bind to immune checkpoint receptors, such as CTLA-4 and PD-1, are proven immunotherapeutic targets. These molecules serve as gateways employed by the body to prevent an overt 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 immune 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.

Contact:

Agenus Inc.
Michelle Linn, 781-674-4541
michelle.linn@agenusbio.com

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