



Agenus Announces Clearance of Investigational New Drug Applications by the FDA for anti-CTLA-4 and anti-GITR Antibodies

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Clinical studies for both checkpoint modulator antibodies allowed to commence

LEXINGTON, Mass.--(BUSINESS WIRE)--Agenus Inc. (NASDAQ: AGEN), an immuno-oncology company developing checkpoint modulator antibodies and cancer vaccines, announced today that the U.S. Food and Drug Administration (FDA) cleared the company's investigational new drug (IND) application for AGEN1884, an immune checkpoint modulator (CPM) antibody that binds to cytotoxic T-lymphocyte antigen-4 (CTLA-4). Clearance was also received for a second CPM antibody partnered with Incyte (NASDAQ: INCY) for INCAGN1876, which targets glucocorticoid-induced TNFR-related protein (GITR). Clinical trials for both candidates are expected to begin in the first half of 2016.

"We are pleased with the prospects of both CTLA-4 and GITR moving rapidly into and through the clinic, and in our efforts to bring profoundly effective medicines to cancer patients," said Garo Armen, PhD, Chairman and CEO of Agenus. "We are also diligently advancing several other product candidates into the clinic and are aiming to begin a number of clinical trials in 2016."

These two compounds were developed utilizing Agenus' state-of-the-art monoclonal antibody platform capabilities and leverage the company's world-class expertise in immuno-oncology and related drug discovery and development. The antibodies were discovered during an earlier collaboration with Ludwig Cancer Research. Recepta, a Brazilian biotech company, was also involved in the collaboration that led to the discovery of AGEN1884, which is partnered with Recepta for certain South American rights. INCAGN1876 is now being co-developed with Incyte.

"CTLA-4 is emerging as an important foundational target for immuno-oncology combination regimens, showing terrific promise when used with other CPMs and cancer vaccines. Our CTLA-4 antagonist antibody, AGEN1884, is a natural potential fit with our expanding vaccine portfolio. This includes Prophage™, slated to enter a randomized placebo-controlled study in newly diagnosed GBM in the second half of 2016, and AutoSynVax™, which we also plan to take into the clinic in the second half of 2016," said Robert B. Stein, MD, PhD, Agenus' President, Research & Development. "I would like to acknowledge the research and development teams at Agenus, and Incyte for GITR, for their tireless efforts to achieve our goal of filing these INDs by the end of 2015."

About Checkpoint Modulators

Promising clinical data from studies employing monoclonal antibodies that bind to checkpoint molecules, such as cytotoxic T-lymphocyte antigen-4 (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, which can be debilitating, and even deadly. 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 immunotherapy 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 manufacturing of monoclonal antibodies that modulate targets of interest. The company's broad portfolio of novel checkpoint modulator 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 studies in newly-diagnosed glioblastoma. The company is collaborating with Merck and Incyte to discover and develop multiple checkpoint modulators. For more information, please visit www.agenusbio.com; information that may be important to investors will be routinely posted on our website.

Forward-Looking Statement

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding planned clinical trial activities of Agenus and its partners, as well as the efficacy of certain product candidates. 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 Agenus' Form 10-Q filed with the Securities and Exchange Commission on November 4, 2015. 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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