Agenus Announces Oral Presentation at ASCO Highlighting Improved Survival with Prophage Immunotherapy in Brain Cancer Compared to Historical Controls

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Improved median Overall Survival and Progression Free Survival observed for Prophage-treated patients with Lower PD-L1 expression on peripheral blood monocytes at baseline

LEXINGTON, Mass.--(BUSINESS WIRE)--Agenus Inc. (NASDAQ:AGEN), an immunology company developing innovative treatments for cancers and other diseases, today announced that data on continuing survival from a Phase 2 study of its Prophage vaccine in glioblastoma multiforme (GBM) has been selected for an oral presentation at the 2015 ASCO Annual Meeting, to be held May 29 – June 2, 2015 in Chicago. The presentation, abstract #2011 entitled "Newly diagnosed glioblastoma patients treated with an autologous heat shock protein peptide vaccine: PD-L1 expression and response to therapy," will be presented during the Clinical Science Symposium at 8:48am CST by Orin Bloch, MD, Khatib Professor of Neurological Surgery and Assistant Professor of Neurological Surgery and Neurology at Northwestern University Feinberg School of Medicine.

Study Highlights

- Patients treated with Prophage added to Standard of Care (SOC) showed significantly longer progression free survival and overall survival compared to historical data for patients receiving SOC alone
- Patients in the study showed a degree of elevation of PD-L1 on their peripheral blood monocytes and in tumor infiltrating macrophages
- In patients who had less PD-L1 on monocytes at baseline, the median Overall Survival (mOS) was approximately 45 months, with a significant proportion of patients alive without progression for more than 3.5 years
- In patients who had more PD-L1 on monocytes at baseline, the mOS was 18 months, still better than expected from historical data

"These are impressive results in a disease that has few effective treatments or promising candidates in development," commented Orin Bloch, M.D. "We're particularly gratified to observe the very impressive survival data in the half of our patients with lower PD-L1 monocyte expression at baseline. Not only is the median Overall Survival much better than expected, but there is a significant proportion of patients who are living longer than expected without progression. We are also intrigued by the possibility that blocking the PD-1 / PD-L1 axis in conjunction with Prophage in patients with elevated PD-L1 may allow the outcomes observed in the lower PD-L1 group to extend to these patients as well."

Study Details

The Phase 2 single-arm trial enrolled forty-six adult patients newly diagnosed with GBM from eight centers in the U.S. Each patient received standard treatment of surgical resection followed by chemoradiation. Within five weeks of completing radiotherapy, patients received weekly Prophage injections for four weeks followed by monthly Prophage injections, and adjuvant temozolomide until the depletion of vaccine or tumor progression. Expression of PD-L1 has been shown to be elevated in patients with GBM, and each patient was also evaluated for PD-L1 expression as a predictor of survival.

The primary endpoint of the trial was overall survival. Median progression-free survival in the trial was 17.8 months (95% CI, 11.3 – 21.6), and median overall survival was 23.8 months (95% CI, 19.8 – 30.2). This compares to a historical overall survival of 14.8 – 18.8 months for patients receiving standard of care alone. The vaccine was well-tolerated in the study with no severe adverse events attributed to the treatment.

The median overall survival for patients with high PD-L1 expression (above the median, 54% of monocytes) was 18.0 months (95% CI, 10.0 – 23.3). Median overall survival for patients with low PD-L1 expression was 44.7 months (95% CI not calculable).

"These data continue to impress, and we're gratified they were selected by ASCO for an oral presentation," commented Dr. Robert Stein, Chief Scientific Officer of Agenus. "Prophage monotherapy, in patients with low PD-L1 expression in peripheral blood monocytes at baseline, appears to show a substantial increase in survival compared to historical controls. Registrational study planning is underway for Prophage, and we will provide further updates later this year."

About Agenus

Agenus is an immunology company developing a series of Checkpoint Modulators for the treatment of patients with cancer, infectious diseases, and other immune disorders, heat shock protein (HSP)-based vaccines, and immune adjuvants. These programs are supported by three synergistic technology platforms. Agenus' internal and partnered checkpoint modulator programs target GITR, OX40, CTLA-4, LAG-3, TIM-3, PD-1 and other undisclosed immune-modulatory targets. The company's proprietary discovery engine Retrocyte Display ^{TM} is used to generate fully human and humanized therapeutic antibody drug candidates. The Retrocyte Display platform uses a high-throughput approach incorporating IgG format human antibody libraries expressed in mammalian B-lineage cells. Agenus recently acquired a powerful yeast antibody display platform termed SECANT, developed by Celexion, LLC. SECANT allows rapid generation of soluble, full-length human antibodies. SECANT and Agenus' mammalian antibody display platform have complementary strengths and further bolster Agenus' abilities to generate and optimize fully human monoclonal antibodies. Agenus' heat shock protein-based vaccines have completed Phase 2 studies in newly diagnosed glioblastoma multiforme, and in the treatment of herpes simplex viral infection; the heat shock protein-based vaccine platform can generate personalized as well as off the shelf products. The company's QS-21 Stimulon® adjuvant platform is extensively partnered with GlaxoSmithKline and with Janssen Sciences Ireland UC and includes several candidates in Phase 2 trials, as well as shingles and malaria vaccines which have successfully completed Phase 3 clinical trials. For more information, please visit www.agenusbio.com, or connect with the company on Facebook, LinkedIn, Twitter and Google+; information that may be

important to investors will be routinely posted in these locations.

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 the upcoming presentation at ASCO, the potential application of the Company's product candidate in the remediation of GBM, and potential future 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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