



Agenus announces collaboration with the National Cancer Institute to evaluate the combination of Pembrolizumab (Keytruda®, Merck & Co., Inc.) with Prophage™ (Agenus Inc.) autologous vaccine

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LEXINGTON, Mass., Jan. 17, 2017 /PRNewswire/ -- Agenus Inc. (NASDAQ: AGEN), an immuno-oncology company with a pipeline of immune checkpoint antibodies and cancer vaccines, today announced a clinical trial collaboration with the National Cancer Institute (NCI). The double-blind, randomized controlled Phase 2 trial will evaluate the effect of Agenus' personalized autologous vaccine candidate, Prophage™ (HSPPC-96), in conjunction with Merck's pembrolizumab on the overall survival rate of patients with newly diagnosed glioblastoma (ndGBM). The trial will be conducted by the Brain Tumor Trials Collaborative (BTTC), a consortium of top academic centers led by Dr. Mark Gilbert, Chief of the Neuro-Oncology Branch at the NCI Center for Cancer Research.



The trial aims to assess the efficacy of PD-1 targeted checkpoint blockade in combination with a heat-shock protein based vaccine candidate in an indication in which this vaccine has shown improved progression-free survival, as presented at ASCO 2015. It is a two-arm trial with one arm receiving pembrolizumab as a monotherapy and a second arm receiving both Prophage and pembrolizumab in combination. Forty-five patients will be randomly assigned to each arm.

Under this collaboration, Agenus will supply Prophage™, Merck will provide pembrolizumab (Keytruda®) and NCI and BTTC member sites will recruit patients and conduct the trial.

About Prophage™

Prophage is an individualized autologous vaccine candidate derived from proteins extracted from the patient's tumor. The vaccine candidate consists of heat shock protein peptide complexes that include the chaperone gp-96 (HSPPC-96) naturally bound to tumor protein fragments. Administration of HSPPC-96 bearing the precise antigenic fingerprint of the patient's particular cancer represents an effective immune education strategy that enhances recognition of a tumor as 'non-self' leading to a potent anti-tumor immune response.

In a Phase 2 study of Prophage monotherapy, patients with ndGBM exhibited an improved progression-free and overall survival as compared to historical control with standard of care.

About KEYTRUDA® (pembrolizumab)

KEYTRUDA is a humanized monoclonal antibody that works by increasing the ability of the body's immune system to help detect and fight tumor cells. KEYTRUDA blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes which may affect both tumor cells and healthy cells. KEYTRUDA is indicated for the treatment of patients with unresectable or metastatic melanoma; for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (TPS ≥50%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations and upon disease progression on or after platinum-containing chemotherapy in patients with NSCLC whose tumors express PD-L1 (TPS ≥1); and for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy. KEYTRUDA is administered as an intravenous infusion every three weeks for the approved indications.

For Safety and Prescribing Information for KEYTRUDA (pembrolizumab), please see http://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_pi.pdf

About Agenus

Agenus is a clinical-stage immuno-oncology company focused on the discovery and development of novel 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 a number of combination approaches that leverage a broad repertoire of antibody therapeutics 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 pre-commercial clinical programs. Agenus is based in Lexington, MA. For more information, please visit www.agenusbio.com; information that may be important to investors will be routinely posted on our website.

About Merck

For 125 years, Merck has been a global health care leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through its prescription medicines, vaccines, biologic therapies, and animal health products, Merck works with customers and operates in more than 140 countries to deliver innovative health solutions. Merck also demonstrates its commitment to increasing access to health care through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with Merck on Twitter, Facebook, YouTube and LinkedIn.

About BTTC

BTTC was created as a network of medical centers with the expertise and strong desire to participate in state-of-the-art clinical trials investigating new treatments for malignant brain tumors. Several additional brain cancer-focused medical centers have since joined the BTTC. These institutions will allow patients across a broad geographic range to participate in cutting-edge clinical trials and more rapidly determine the benefits of various therapies.

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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