Advantagene Announces ASCO Presentation of Positive Data from Phase 1b Clinical Trial using Its GMCI® technology for Patients with Malignant Pleural Effusion

***Auburndale, MA*, June 4, 2016 -** Advantagene, Inc., a clinical-stage biotechnology company developing a novel cancer immunotherapy platform for the treatment of solid tumors, announced today the presentation of safety and interim efficacy data from a Phase 1b clinical trial of its novel Gene Mediated Cytotoxic Immunotherapy (GMCI®) in combination with standard of care chemotherapy in patients with malignant pleural effusion (MPE). The study is being conducted in collaboration with the University of Pennsylvania.

The primary end-point of this dose escalation trial was to evaluate the safety of GMCI® using intra-pleural delivery of aglatimagene besadenovec to stimulate an anti-tumor immune response followed by standard chemotherapy. Eligible patients had malignant pleural effusion requiring a pleural catheter. Nineteen patients were enrolled and completed therapy, 3 in each of 3 cohorts followed by an additional 10 patient expansion of the third cohort. Patients in cohort 2 (high vector dose group) experienced symptoms related to immune stimulation, including transient cytokine release syndrome (CRS), with fever, nausea and chills (grade 2) plus hypotension in one patient. In cohort 3, the addition of celecoxib effectively controlled the CRS symptoms. The study included fourteen malignant mesothelioma patients, all with poor prognostic factors including sarcomatoid histology, multiply relapsed or not surgical candidates due to comorbidities. The study also enrolled four stage 4 non-small cell lung cancer (NSCLC) patients and one stage 4 breast cancer patient. In the high dose group, disease control rate was 79% with partial response by RECIST criteria in five patients (36% PR rate), three with mesothelioma and two NSCLC. Median overall survival was 13.6 months for the high dose group. Seven patients are still alive and continue in active follow up (5-21months), including three NSCLC patients with progression free survival of 6.8-12.9 months and overall survival at 12.9-17.4 months. These results will be presented this weekend by Dr. Charu Aggarwal, MD, MPH, Assistant Professor in Hematology-Oncology at University of Pennsylvania in a poster presentation (abstract # 3081) at the 2016 American Society of Clinical Oncology (ASCO) meeting held in Chicago.

“We are encouraged with the data from this study and, while still early, it supports our hypothesis that Advantagene’s GMCI immunotherapy can be safely coupled with standard of care chemotherapy to elicit a robust and durable benefit in patients with this very aggressive and difficult to treat malignant condition” said Dr. Aggarwal.

“This Phase 1b safety study has provided very promising data” stated Dr. Laura K. Aguilar, M.D., Ph.D., Chief Medical Officer of Advantagene. “Patients in the high dose group had cytokine release symptoms, indicating immune stimulation, and these were easily managed with celecoxib. The interim survival data from patients with poor prognosis mesothelioma and from patients with non-small cell lung cancer, a particularly lethal disease, are quite encouraging. We look forward to the maturation of the data. Based on the current results, we are already planning additional studies to further develop this promising new therapy in patients with lung cancer, mesothelioma and other MPE indications.”

About Malignant Pleural Effusion (MPE)

Malignant pleural effusions are a frequent complication in advanced stages of malignancies. Lung and breast cancers are the most common etiologies of MPE, and MPE almost always develops in patients with malignant mesothelioma. The presence of MPE indicates an advanced stage of disease and thus reduced survival, usually ranging from 3-12 months depending on the originating malignancy. It is highly debilitating and often requires palliative treatment to facilitate patient breathing and alleviate cough or pain. Symptomatic relief is often achieved by removing large amounts of fluid that accumulates in the pleural space using the procedure with least morbidity within the limited survival expected for the patient. In patients that can tolerate anesthesia, this may include the placement of a tube for continuous drainage. After fluid draining, if survival expectancy is more than three months, pleurodesis a chemical or physical inflammatory procedure aiming to create fibrosis in the pleural space to prevent re-accumulation of fluid, may be attempted. There are no curative treatments for MPEs.

About Advantagene and Gene Mediated Cytotoxic Immunotherapy®

Advantagene is a Massachusetts based biotechnology company developing its proprietary Gene Mediated Cytotoxic Immunotherapy® (GMCI™) platform technology for the treatment of solid tumors. GMCI™ is an "off the shelf" low toxicity immunotherapy that stimulates a patient's own immune system to generate a precise, robust and durable response against his or her individual cancer. Advantagene is conducting a registration clinical trial with its lead candidate, ProstAtak®, under a Special Protocol Assessment approved by the U.S. Food and Drug Administration, for the treatment of localized prostate cancer patients with intermediate to high risk disease choosing radiation therapy. If proven efficacious, ProstAtak® will be the first and only therapeutic pharmaceutical available for newly diagnosed localized prostate cancer patients. The company is conducting additional GMCI™ clinical studies in lung malignancies and MPE, pancreatic cancer, brain cancer, and localized prostate cancer patients choosing active surveillance, in each case with positive clinical results to date. For more information about Advantagene and our GMCI™ cancer immunotherapy program please visit www.advantagene.com.

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