

Advantagene Launches Clinical Study in Patients with NSCLC

Auburndale, MA, June 27, 2017 - Advantagene, Inc., a clinical-stage biotechnology company, announced today that the first patient has been treated in a Phase 1b clinical study of its novel immuno-oncology product, Gene Mediated Cytotoxic Immunotherapy (GMCI™), in patients with non-small cell lung cancer (NSCLC). GMCI is an investigational immuno-oncology therapy that includes an intratumoral injection of aglatimagene besadenovec (AdV-tk) followed by systemic administration of an anti-herpetic prodrug. Extensive clinical and pre-clinical data suggests that neoadjuvant GMCI can induce significant anti-tumor immune responses and improve post-operative outcomes.

The study, LuTK01, is being conducted at the Hospital of the University of Pennsylvania under the direction of Dr. Sunil Singhal. LuTK01 is a Phase 1b dose escalation study to evaluate GMCI in subjects with high risk resectable NSCLC in combination with standard of care surgery. The primary clinical end-point of LuTK01 is to evaluate the safety of GMCI when combined with standard surgery for NSCLC. Immunogenic, genomic and pathologic responses will also be evaluated to further inform the design of follow-on clinical studies in NSCLC.

This study follows on promising results from a recent study, MpeTK01, using intrapleural GMCI to treat malignant mesothelioma and metastatic lung cancer. In MpeTK01, also performed at the University of Pennsylvania, 4 of 19 patients had NSCLC metastatic to the pleural cavity. Patients with this condition generally have an expected survival of 3-5 months, yet 3 of the 4 NSCLC patients had overall survival of more than 24 months from treatment, including one that remains alive 29 months from treatment. “The data generated in the small MpeTK01 study is very encouraging. Coupled with GMCI’s compelling clinical data in other indications, there is a strong rationale for moving forward with GMCI in NSCLC patients,” stated Dr. Singhal.

Advantagene currently has ongoing clinical studies using GMCI to treat other solid tumor indications, including a Phase III study in prostate cancer and Phase I-II studies in brain and pancreatic cancers. “The expansion of our GMCI platform to NSCLC patients is an important milestone for Advantagene and further validates the breadth and utility of the technology,” stated Dr. Estuardo Aguilar-Cordova, Chairman and CEO of Advantagene.

For more information about the LuTK01 study, please visit www.clinicaltrials.gov and use reference identifier NCT03131037.

About NSCLC

Lung cancer is the leading cause of cancer-related death in the United States and throughout most of the world. The American Cancer Society estimates that in the United States in 2017 there will be 222,500 diagnoses of lung cancer and 155,870 deaths. These projections highlight the extraordinary lethality of lung cancer as only 17% survive more than five years. About eighty-percent of all lung cancer cases are of non-small cell histology. Surgery remains the only way to effectively treat patients, but only 1 of 3 patients diagnosed with NSCLC qualify for

surgery. Even in the surgical candidates, however, prognosis is poor despite the use of aggressive adjuvant chemotherapy and radiation protocols and the limited, yet significant, success of new immunotherapy therapeutics. Cancer recurrences after surgery for NSCLC are frequent (~50% of patients) and are due to micrometastatic disease that is not removed by oncologic resection. Traditional adjuvant approaches (i.e. chemotherapy and radiation) have led to only modest reductions in metastatic recurrence rates. Consequently, new approaches to treat the disease are required.

About Advantagene, Inc.

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 robust response against his or her cancer, causing tumor cell death and clearance. The company is conducting additional GMCI clinical studies in prostate, lung, pancreas and brain cancers. Advantagene is conducting a registration clinical trial with its clinical GMCI candidate, ProstAtak®, for the treatment of newly diagnosed prostate cancer patients under a Special Protocol Assessment approved by the U.S. Food and Drug Administration. If proven efficacious, ProstAtak® will be the first and only therapeutic pharmaceutical available for newly diagnosed prostate cancer patients. For more information about Advantagene and our GMCI cancer immunotherapy program please visit www.advantagene.com.

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