Candel Therapeutics Announces Presentation of Clinical Data for GMCI in NSCLC at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting

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Needham, MA -- Candel Therapeutics, a clinical-stage biotechnology company, developing novel immune-based cancer therapeutics, today announced presentation at the annual meeting of the American Society of Clinical Oncology of data with the Company's lead product candidate, GMCI. The study, led by Dr. Sunil Singhal and Dr. Steven Albelda (University of Pennsylvania, PA), evaluated endobronchial delivery of GMCI as an immunostimulant neoadjuvant to surgery for non-small cell lung cancer (NSCLC) patients. The approach was well tolerated and induced a potent increase in CD8+ T cells in the tumors with significant up-regulation of T cell activation markers. Extraordinarily, it also produced a significant systemic signal of immune activation in peripheral blood. Increased expression of immune checkpoint receptors, another sign of immune activation, were also seen in the treated tumors and peripheral blood. "The results are very encouraging and support the concept that "in situ vaccination" using GMCI has the potential to activate T cells systemically and within the lung cancer tumors," said Dr. Albelda.

GMCI has also shown similar immune activation and promising outcome results in other tumor types, including prostate, brain and pancreatic cancer. In prostate cancer, GMCI is being analyzed in a phase 3 study in combination with radiation therapy. In a recent Phase 2 study in malignant glioma, GMCI demonstrated a significant overall survival benefit, especially in patients where the tumor load had been substantially reduced by surgery. GMCI plus anti-PD-1 checkpoint inhibitor (CPI) resulted in significant increases in responses and survival in preclinical studies. A trial is ongoing of GMCI plus nivolumab in malignant glioma in combination with standard of care.

"These results point to a new opportunity for improving outcomes in patients with lung cancer," said Dr. Estuardo Aguilar-Cordova, Chief Executive Officer of Candel. "GMCI seems to turn 'cold' tumors into immune responsive 'hot' tumors. GMCI has the potential to improve the outcome for NSCLC patients, and especially for the 60-70% of patients that don't initially respond to CPIs. We are very enthusiastic for a trial that will be starting at multiple sites in the US later this year for patients with stage III/IV NSCLC that are not responding to CPI."

About Candel Therapeutics

Candel Therapeutics is a Massachusetts based biotechnology company developing its proprietary immuno-oncology platforms, including its Gene Mediated Cytotoxic Immunotherapy (GMCI™) platform and rQNestin34.5 platform, for the treatment of solid tumors.

GMCI™ is an “off the shelf” low toxicity adenovirus based immunotherapy that causes immunogenic tumor cell death, stimulating a hyper-immunogenic microenvironment and generating a personalized, robust and precise systemic response from the patient’s own immune system against his or her cancer. GMCI™ has been evaluated in 11 completed clinical trials and 5 ongoing clinical trials across multiple indications including prostate, brain, pancreas and lung cancers. With over 1,200 patient doses in 650 patients, GMCI™ has meaningful evidence suggesting it is well tolerated and safe. These studies include a registration clinical trial for the treatment of localized prostate cancer patients under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration. If proven efficacious, this product candidate will be the first and only therapeutic pharmaceutical available for localized prostate cancer patients.

rQNestin34.5 is an immuno-oncology approach that uses a genetically modified oncolytic herpes simplex virus engineered for enhanced potency. Conditional ICP34.5 expression in the presence of Nestin greatly improves replication and oncolytic activity of HSV. This product candidate is currently being tested in a Phase 1 clinical study in patients with recurrent malignant glioma.
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