Candel Therapeutics and Partnership for Accelerating Cancer Therapies (PACT) to Collaborate on Lung Cancer Trial for CAN-2409

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- *Partnership for Accelerating Cancer Therapies to conduct extensive biomarker analysis for ongoing phase 2 clinical trial in non-small cell lung cancer*
- *Trial combines CAN-2409 with immune checkpoint inhibitor treatment after inadequate tumor response to initial checkpoint inhibitor therapy*
- *Collaboration may identify early markers of response and inform patient selection for treatment*

NEEDHAM, Mass., Dec. 10, 2021 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Nasdaq: CADL), a late clinical stage biopharmaceutical company developing novel oncolytic viral immunotherapies, today announced a collaboration with Partnership for Accelerating Cancer Therapies (PACT) and the Cancer Immune Monitoring and Analysis Centers – Cancer Immunologic Data Commons (CIMAC-CIDC) to profile the biomarker response to a combination of CAN-2409 + valacyclovir in combination with anti-PD-1 and PD-L1 immune checkpoint inhibitors in patients with non-small cell lung cancer (NSCLC).

Analysis of longitudinal biologic samples from a Candel phase 2 clinical trial will be performed by the CIMAC-CIDC research centers and sponsored by PACT. The assays proposed include in depth immunophenotyping of serial lung biopsies and peripheral blood samples obtained during the clinical trial. Candel's clinical trial in NSCLC is designed to assess the tumor response to CAN-2409 when added to anti-PD-1 or PD-L1 immune checkpoint inhibitor (ICI) treatment after patients have inadequately responded to ICI with or without chemotherapy. The trial comprises three cohorts; 1) patients whose best response to ICI treatment has been stable disease; 2) patients who have initially responded to ICI treatment, but whose disease is now progressing; and 3) patients who have refractory disease, meaning they are progressing rapidly despite ICI treatment. In each of these settings, minimal to no response is expected from further ICI treatment. The collaboration will analyze samples from each of these cohorts with the aim to identify early biological indicators of response and further stratify potential responders to treatment.

"We have shown that local administration of CAN-2409 monotherapy induces significant remodeling of the tumor immune microenvironment coupled with systemic activation of the immune response," said Francesca Barone, MD, PhD, Vice President and Head of Research at Candel. "We are honored by the selection of our clinical trial by the PACT consortium, which provides an important validation of Candel's approach to embed the highest levels of scientific rigor in our clinical trials. The data generated through this collaboration will broaden our understanding of the biological response to combination therapy of CAN-2409 with ICI, as we endeavor to bring effective new treatment options to patients with cancer."

About PACT

The Partnership for Accelerating Cancer Therapies (PACT) is a five-year public-private research collaboration launched by the National Institutes of Health, the Foundation for the National Institutes of Health (FNIH), and 12 leading pharmaceutical companies as part of the Cancer Moonshot^{SM} Research Initiatives. The PACT initiative is partnered with the Cancer Immune Monitoring Analysis Centers (CIMACs) and the Cancer Immunologic Data Commons (CIDC) Network to develop and validate a set of standardized and harmonized biomarker assays that profile the response to immuno-oncology interventions, including combination therapies, oncolytic viral immunotherapy, and other novel immunotherapy treatments.

For more information about PACT, visit https://fnih.org/pact.

About CAN-2409

CAN-2409, Candel's most advanced oncolytic viral immunotherapy candidate, is a replication-deficient adenovirus that delivers the herpes simplex virus thymidine kinase (HSV-tk) gene to cancer cells. HSV-tk is an enzyme that locally converts orally administered valacyclovir into a toxic metabolite that kills nearby cancer cells. The intra-tumoral administration results in the release of tumor-specific neoantigens in the microenvironment. At the same time, the adenoviral serotype 5 capsid protein elicits a strong pro-inflammatory signal in the tumor microenvironment. This creates the optimal conditions to induce a specific CD8+ T cell mediated response against the injected tumor and uninjected distant metastases for broad anti-tumor activity.

Because of its versatility, CAN-2409 has the potential to treat a broad range of solid tumors. Monotherapy activity as well as combination activity with standard of care radiotherapy, surgery, chemotherapy, and immune checkpoint inhibitors have previously been shown in several preclinical and clinical settings. Furthermore, CAN-2409 presents a favorable tolerability profile; more than 700 patients have been dosed to date, supporting the potential for combination with other therapeutic strategies without inordinate concern of overlapping adverse events. Currently, Candel is evaluating the effects of treatment with CAN-2409 in non-small cell

lung cancer, high-grade glioma, pancreatic cancer, and localized, non-metastatic prostate cancer in ongoing clinical trials.

For more information on this clinical study, please visit: https://www.clinicaltrials.gov/ct2/show/NCT04495153

About Candel Therapeutics

Candel is a late clinical stage biopharmaceutical company focused on helping patients fight cancer with oncolytic viral immunotherapies. Candel's engineered viruses are designed to induce immunogenic cell death through direct viral-mediated cytotoxicity in cancer cells, thus releasing tumor neo-antigens while creating a pro-inflammatory microenvironment at the site of injection. Candel has established two oncolytic viral immunotherapy platforms based on novel, genetically modified adenovirus and herpes simplex virus (HSV) constructs, respectively. CAN-2409 is the lead product candidate from the adenovirus platform and CAN-3110 is the lead product candidate from the HSV platform. The enLIGHTEN™ Discovery Platform is based on Candel's HSV technology.

For more information about Candel, visit www.candeltx.com.

Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements," within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, express or implied statements regarding the timing and advancement of development programs, include key data readout milestones; expectations regarding the therapeutic benefit of its programs; and expectations regarding cash runway and expenditures. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those risks and uncertainties related to the timing and advancement of development programs; expectations regarding the therapeutic benefit of the Company's programs; the Company's ability to efficiently discover and develop product candidates; the Company's ability to obtain and maintain regulatory approval of product candidates; the Company's ability to maintain its intellectual property; the implementation of the Company's business model, and strategic plans for the Company's business and product candidates, and other risks identified in the Company's SEC filings, including the Company's Quarterly Report on Form 10-Q filed on November 12, 2021, and subsequent filings with the SEC. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent the Company's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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