Candel Therapeutics Announces Release of Initial Data on CAN-2409 in a Phase 2 Clinical Trial Showing Cytotoxic T Cell Response and Disease Control in Patients with Non-Small Cell Lung Cancer

- *Disease control rate of 87.5 percent achieved in patients who were all progressing on anti-PD-1 therapy at trial entry*
- *Durable disease stabilization that was ongoing at data cutoff in 62.5 percent of the patients who entered the study with progressive disease and were followed for a minimum of 12 weeks*
- *Partial response in 15 percent of the patients*
- *Evidence of tumor regression in both injected and uninjected lesions*
- *Induction of local and systemic cytotoxic T cell response after experimental treatment with CAN-2409*

Candel to host investor event and webcast at 6:30 am CDT on June 4

NEEDHAM, Mass., May 26, 2022 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Nasdaq: CADL), a late clinical stage biopharmaceutical company developing novel oncolytic viral immunotherapies, today announced the publication of abstract #9037 at the American Society of Clinical Oncology (ASCO) Annual Meeting taking place June 3-7, 2022, in Chicago. The abstract summarizes initial data as of January 10, 2022, from Candel's open-label phase 2 clinical trial evaluating CAN-2409 in combination with anti-PD-1 or PD-L1 agents in patients with stage III/IV non-small cell lung cancer (NSCLC) who have had an inadequate response to immune checkpoint inhibitor treatment. The data presented in the poster will include additional data not included in the abstract from a total of 20 patients as of April 20, 2022, including 16 patients from cohort 2.

"The achievement of an 87.5 percent disease control rate in patients whose cancer was progressing on anti-PD-1 treatment at enrollment bolsters the evidence of CAN-2409's potential to induce immunization against cancer neoantigens in both injected tumors and uninjected metastases so that resistance to checkpoint blockade can be overcome," said Paul Peter Tak, MD, PhD, FMedSci, President and CEO of Candel. "The occurrence of abscopal

effects and clinically meaningful and durable activity, supported by significant biomarker responses and prior monotherapy activity data, strengthens our belief that this investigational agent has the potential to improve outcomes for patients with NSCLC who are progressing on anti-PD-1 agents."

Experimental treatment with CAN-2409 plus valacyclovir in combination with anti-PD-1 agents appeared to be well tolerated. The most common treatment-related adverse events were transient flu-like symptoms, such as chills, fever and fatigue, with no grade 4 and two grade 3 events reported.

Additional data highlights include:

- Most patients experienced a reduction in tumor burden.
- There were three objective responses in cohorts 1 and 2 (patients with stable disease or progressive disease upon entry, respectively). A fourth patient with PR initially reported in the abstract became ineligible for RECIST assessment due to an irradiated lesion; the patient still showed an absence of disease progression for more than 6 months.
- Two of the three patients with a PR had PD-L1 expression below 1 percent, the third being unknown; 19 of 20 patients in the trial had negative or low PD-L1 expression.
- CAN-2409 treatment induced 1) increased tumor infiltration by cytotoxic T cells, 2) a systemic increase in actively proliferating, granzyme B positive T cells, 3) an increase in interferon gamma producing effector cells in both CD4+ and CD8+ compartments, and 4) increased levels of soluble granzymes A, B and H, all consistent with the hypothesized mechanism of action of CAN-2409.

"As a physician who cares for patients with NSCLC, I am frequently confronted with the problem faced by the majority of patients with lung cancer who ultimately progress on immune checkpoint therapy," said Daniel Sterman, MD, Professor at NYU Langone Heath, and a principal investigator for the phase 2 clinical trial. "The data from this clinical trial are incredibly exciting, suggesting that the addition of CAN-2409 to pembrolizumab or nivolumab containing treatment regimens in patients experiencing progression may offer a new therapeutic option where few good alternatives exist. Importantly, CAN-2409 was administered only two times in this setting, with intratumoral administration providing a simple and straightforward approach."

Details on the abstract are below:

- **Abstract Title:** First report of safety/tolerability and preliminary antitumor activity of CAN-2409 in inadequate responders to immune checkpoint inhibitors for stage III/IV NSCLC
- **Presenter:** Charu Aggarwal, MD, MPH, Associate Professor of Lung Cancer Excellence, Perelman School of Medicine, University of Pennsylvania
- **Session Date and Time:** June 6, 2022, from 8:00 - 11:00 am CDT
- **Session Title:** Lung Cancer – Non-Small Cell Metastatic
- **Location:** McCormick Convention Center, Hall A
- **Abstract Number:** 9037

Candel also announced that an in-person and webcast investor event will be held on **Saturday, June 4, 2022, from 6:30 – 7:45 am CDT.**

Key speakers will be:

- Dr. Roy Herbst, Professor of Medical Oncology and Chief of Medical Oncology at the Yale Cancer Center, and member of Candel's Research Advisory Board
- Dr. Daniel Sterman, Professor of Pulmonary and Critical Care Medicine, at New York University (NYU), Director of the Multidisciplinary Pulmonary Oncology Program at NYU Langone Health, and a principal investigator on the phase 2 clinical trial
- Dr. Paul Peter Tak, President and CEO of Candel Therapeutics

The webcast and slides will be accessible live under "Events and Presentations" on the Investors page of the company's website at https://ir.candeltx.com/news-and-events/events-and-presentations or by clicking here. A replay will be available on the website for approximately 90 days after the event.

Dr. Charu Aggarwal is serving as the co-principal investigator of this phase 2 clinical trial. For more information on the clinical trial please visit: https://clinicaltrials.gov/ct2/show/NCT04495153

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.

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 such as CAN-2409, including key data readout milestones; expectations regarding the therapeutic benefit of its programs; potential regulatory strategies and plans; 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 Registration Statement on Form S-1, the Company’s Quarterly Report on Form 10-Q filed on May 12, 2022, 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. This press release includes certain disclosures about initial data that is subject to change and may not reflect data from future clinical trials.

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