Candel Therapeutics Announces It Expects to Report Topline Data from its Phase 2 Clinical Trial of CAN-2409 in Non-Small Cell Lung Cancer in the Second Quarter of 2024

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- *Based on forthcoming completion of patient enrollment and duration of follow-up in Cohort 2 from the phase 2 trial in late-stage NSCLC*

NEEDHAM, Mass., June 13, 2023 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a clinical stage biopharmaceutical company focused on developing viral immunotherapies to help patients fight cancer, today announced that, in the second quarter of 2024, it expects to report topline overall survival data from its ongoing, open-label, phase 2 clinical trial of CAN-2409 plus valacyclovir in combination with continued immune checkpoint inhibitor treatment (ICI) in patients with non-resectable, stage III/IV non-small cell lung cancer (NSCLC) who progressed while on treatment with PD-(L)1 inhibitor therapy (Cohort 2).

“As we approach full enrollment of a cohort of approximately 40 patients with documented radiographic progression on PD-(L)1 inhibitor treatment, we expect that we will be able to report topline overall survival data for this cohort in the second quarter of 2024,” said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. “In conjunction with this topline data, we will assess whether the effect on tumor biology previously reported could translate into improved survival, which we believe is what matters to patients and regulators. We remain optimistic that this expected dataset could help initiate discussions with regulators about a future potentially registrational clinical trial in this indication of serious unmet disease.”

Dr. Tak continued, “In the near-term, we continue to expect to present additional clinical and immunological biomarker activity data from this clinical trial in the third quarter of this year. To date, we have reported mechanistic evidence that CAN-2409 plus valacyclovir can induce a systemic anti-tumor response in ICI inadequate responders, which had shown improvement of injected and uninjected tumor size and an overall beneficial effect on tumor growth over time.”

In 2022, the Company presented preliminary evidence that CAN-2409 plus valacyclovir, when added to first line PD-(L)1 inhibitor therapy, in late-stage NSCLC patients showing radiographic progression despite at least 18 weeks of ICI treatment, is able to 1) induce local and systemic reduction in the size of tumor lesions, with an abscopal effect in uninjected lesions (*Aggarwal C et al. J Clin Oncol 2022;40(16) Suppl:9037 [ASCO abstract]*), and 2) change the tumor growth trajectory after follow up, and significantly decrease the monthly rate of tumor growth *(Aggarwal C et al. Virtual R&D Day, December 2022)*. These data supported the application for Fast Track designation, granted by the U.S. Food and Drug Administration for this program in April 2023. The Company remains on target to present additional clinical and immunological biomarker activity data in the third quarter of 2023. Based on enrollment rates and duration of follow-up in Cohort 2, the Company expects to present topline data for overall survival in this Cohort, a key clinical endpoint of interest to regulatory bodies in this patient population, in the second quarter of 2024.

CAN-2409 is an investigational off-the-shelf viral immunotherapy designed to induce an individualized, systemic immune response against the patient’s specific tumor. CAN-2409 plus valacyclovir in combination with continued PD-(L)1 inhibitors is being evaluated in an ongoing, open-label phase 2 clinical trial (NCT04495153) in patients with non-resectable, stage III/IV NSCLC and an inadequate response to ICI treatment.

About Candel Therapeutics

Candel is a clinical stage biopharmaceutical company focused on developing viral immunotherapies that elicit a systemic anti-tumor immune response to help patients fight cancer. 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 clinical stage viral immunotherapy platforms based on novel, genetically modified adenovirus and herpes simplex virus (HSV) gene 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. Candel’s enLIGHTEN™ Discovery Platform is a systematic, iterative HSV-based discovery platform leveraging human biology and advanced analytics to create new viral immunotherapies for solid tumors.

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

About CAN-2409

CAN-2409, Candel’s most advanced viral immunotherapy candidate, is a replication-defective adenovirus that is designed to deliver 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 is designed to create the optimal conditions to induce an individualized and 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. Encouraging 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, more than 950 patients have been dosed with CAN-2409 with a favorable tolerability profile 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, pancreatic cancer, and localized, non-metastatic prostate cancer in ongoing clinical trials. The U.S. Food and Drug Administration granted Fast Track designation for CAN-2409 plus valacyclovir in combination with pembrolizumab in order to improve survival or delay progression in patients with stage III/IV non-small cell lung cancer

who are resistant to first line PD-(L)1 inhibitor therapy and who do not have activating molecular driver mutations or have progressed on directed molecular therapy.

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, including the timing and outcome of interactions with regulatory authorities with respect to the Company’s product candidates and programs and expectations regarding the therapeutic benefit of its programs. 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 most recent Quarterly Report on Form 10-Q filed with the SEC, 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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