Candel Therapeutics Announces Restructuring to Prioritize Resources on Key Value Drivers for Expanded Development of CAN-3110, the enLIGHTEN™ Discovery Platform, and Key Clinical Readouts for CAN-2409

Nov 28, 2023

- *Decreases workforce by approximately 50% and reduces commercial manufacturing expenses to prioritize spend towards topline clinical data readouts for CAN-2409 in non-small cell lung cancer, pancreatic cancer, and prostate cancer in 2024*
- *Prioritizes development of CAN-3110 in recurrent high-grade glioma and initiation of investigational new drug (IND)-enabling studies in second indication*
- *Plans to broaden discovery partnership opportunities based on the enLIGHTEN™ Discovery Platform*
- *Extends cash runway into the fourth quarter of 2024*

NEEDHAM, Mass., Nov. 28, 2023 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a clinical stage biopharmaceutical company focused on developing multimodal biological immunotherapies to help patients fight cancer, today announced a strategic restructuring to focus on continuation and expansion of development of CAN-3110 as well as the enLIGHTEN™ Discovery Platform, while reducing the Company's workforce and expenses associated with enabling commercial readiness of CAN-2409. The Company expects to present initial activity and biomarker data for repeated injections of CAN-3110 in recurrent high-grade glioma in the second half of 2024 and new data for the second drug candidate based on the enLIGHTEN™ Discovery Platform in Q3 2024. The Company plans to continue to collect clinical data for key readouts for CAN-2409 in non-small cell lung cancer (NSCLC), with topline overall survival data of the open label phase 2 clinical trial expected in Q2 2024; pancreatic cancer, with an update on overall survival based on an interim analysis of the randomized, open label clinical trial in Q2 2024; and prostate cancer, with topline data for both fully enrolled randomized, blinded, placebo-controlled phase 2 and phase 3 clinical trials in Q4 2024.

Based on the encouraging clinical activity data for CAN-2409, the large number of patients that might benefit from this treatment, and the investments needed for commercialization, the Company plans to explore the right partnering opportunities for the future development of this asset.

To focus on delivering on the value-creating catalysts in 2024, on November 28, 2023, Candel implemented a reduction in its workforce of approximately 50%. The Company estimates that it will incur a one-time restructuring charge of approximately $0.7 million in the fourth quarter of 2023 related to severance and healthcare and related benefits for terminated employees. Candel expects that the reduction in workforce, coupled with the reduced operating costs, will enable the Company's existing cash resources to fund its revised operating plan into the fourth quarter of 2024, enabling the achievement of key catalysts next year.

"This decision, unfortunately, impacts our workforce," said Paul Peter Tak, MD PhD FMedSci, President and CEO of Candel. "I want to express my sincere gratitude for the very important work and valuable contributions of our departing employees. They have done amazing work advancing the pipeline and developing our investigational medicines. In the current market, we need to remain laser focused on delivering on our value-creating inflections points, while managing our expenditures. We have proof of mechanism and proof of concept in each indication that we are currently pursuing, and the value created in the past years will be leveraged in the multiple data readouts planned for 2024."

About the enLIGHTEN™ Discovery Platform

Candel's enLIGHTEN™ Discovery Platform is a systematic, iterative herpes simplex virus (HSV)-based discovery platform leveraging human biology and advanced analytics to create new multimodal biological immunotherapies for solid tumors. In October 2022, the Company announced a discovery collaboration with the University of Pennsylvania Center for Cellular Immunotherapies to identify how viral immunotherapy could enhance the efficacy of CAR-T cell therapy in solid tumors. The enLIGHTEN™ Discovery Platform is designed to deconvolute the complexity of the tumor microenvironment to identify druggable properties that correlate with clinical outcomes. These discoveries are rapidly translated into optimized multi-gene payloads of tumor modulators that are tailored for specific indications, disease stage, and rationally designed therapeutic combinations. During the Society for Immunotherapy of Cancer (SITC) 2023 Annual Meeting and the International Oncolytic Virus Conference in November 2023, Candel presented encouraging data on the discovery pipeline, demonstrating the effects of Alpha 201-macro-1, an investigational locally delivered biological oncolytic therapeutic designed to interfere with the CD47/SIRP1a pathway, in a mouse model of breast cancer.

About CAN-3110

CAN-3110 is a first-in-class, replication-competent herpes simplex virus-1 (HSV-1) oncolytic viral immunotherapy candidate

designed with dual activity for oncolysis and immune activation in a single therapeutic. Its activity is conditional to the expression of Nestin in cancer cells. CAN-3110 is being evaluated in a phase 1 investigator-sponsored clinical trial in patients with recurrent HGG. Earlier this month, the Company announced that Nature published results from this clinical trial. CAN-3110 was well tolerated with no dose-limiting toxicity reported and CAN-3110 plus prodrug was associated with improved survival. Positive HSV-1 serology was a predictor of response and was associated with improved survival. Increased infiltrating immune cells in the tumor microenvironment and expansion of the T cell repertoire after treatment were also associated with improved survival. In the clinical trial, the investigators observed a nearly doubling of the expected median overall survival after a single CAN-3110 injection, compared to historical reports of less than 6 to 9 months in this therapy-resistant condition. By comparison, survival in the anti-HSV1 positive patients treated with CAN-3110 was over 14 months. The Company and academic collaborators are currently evaluating the effects of multiple CAN-3110 injections in recurrent HGG, supported by the Break Through Cancer foundation, and expect initial results in H2 2024.

Candel will also initiate IND-enabling work in a second indication characterized by Nestin expression.

About CAN-2409

CAN-2409, Candel's most advanced multimodal biological immunotherapy candidate, is an investigational off-the-shelf replication-defective adenovirus designed to deliver the herpes simplex virus thymidine kinase (HSV-tk) gene to a patient's specific tumor and induce an individualized, systemic immune response against the disease. HSV-tk is an enzyme that locally converts orally administered valacyclovir into a toxic metabolite that kills nearby cancer cells. Together, this regimen is designed to induce an individualized and specific CD8+ T cell mediated response against the injected tumor and uninjected distant metastases for broad anti-tumor activity, based on in situ vaccination against a variety of tumor antigens. 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 NSCLC, borderline resectable pancreatic cancer, and localized, non-metastatic prostate cancer in ongoing clinical trials.

About Candel Therapeutics

Candel is a clinical stage biopharmaceutical company focused on developing off-the-shelf multimodal biological immunotherapies that elicit an individualized, systemic anti-tumor immune response to help patients fight cancer. Candel has established two clinical stage multimodal biological immunotherapy platforms based on novel, genetically modified adenovirus and HSV gene constructs, respectively. CAN-3110 is the lead product candidate from the HSV platform and is currently in an ongoing investigator-sponsored phase 1 clinical trial in recurrent HGG. In addition, 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. CAN-2409 is the lead product candidate from the adenovirus platform and is currently in ongoing clinical trials in NSCLC (phase 2), borderline resectable pancreatic cancer (phase 2), and localized, non-metastatic prostate cancer (phase 2 and phase 3).

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 current and future development programs, including the timing and availability of additional data, the possibility to use early biological readouts as predictor of clinical response and expectations regarding the therapeutic benefit of its programs, the estimated charges and costs expected to be incurred in connection with the Company's strategic restructuring efforts, the anticipated cost savings resulting from the Company's strategic restructuring efforts, the Company's potential pursuit of a strategic partnership for the development of CAN-2409, and the Company's cash runway. 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, results and costs related to the Company's strategic restructuring efforts; the timing and advancement of current and future development programs; that final data from our pre-clinical studies and completed clinical trials may differ materially from reported interim data from ongoing studies and trials; 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

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