Candel Therapeutics Completes Enrollment in Phase 3 Clinical Trial of CAN-2409 in Combination with Valacyclovir for the Treatment of Intermediate-High Risk Localized Prostate Cancer

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NEEDHAM, Mass., Sept. 7, 2021 --(GLOBE NEWSWIRE)-- Candel Therapeutics, Inc. ("Candel") (Nasdaq: CADL), a late clinical stage biopharmaceutical company developing novel oncolytic viral immunotherapies, today announced that it has completed patient enrollment for its pivotal phase 3 study of CAN-2409 immunotherapy in patients with intermediate-high risk localized prostate cancer. This placebo-controlled, randomized clinical trial is evaluating CAN-2409 treatment in combination with valacyclovir added to upfront standard of care external beam radiation therapy for patients with localized prostate cancer compared to standard of care radiation therapy alone.

"The combination of CAN-2409 with radiation therapy has been shown to create an immune stimulatory environment and is designed to activate the body's immune system to recognize and destroy cancer cells," said Paul Peter Tak, M.D., Ph.D., FMedSci, President and Chief Executive Officer of Candel Therapeutics. "There is a significant need in patients with localized, non-metastatic prostate cancer for novel therapies that will improve outcomes, while reducing the need for long-term androgen deprivation therapy with its associated side effects. We believe CAN-2409 could improve disease outcome in patients with prostate cancer, and we look forward to the results of this potentially registrational clinical trial in 2024."

The primary endpoint of the study is disease-free survival. Secondary endpoints include prostate cancer specific survival, overall survival, freedom from biochemical failure, patient reported health-related quality of life, and safety.

For more information about this study, please visit:
https://www.clinicaltrials.gov/ct2/show/NCT01436968

About CAN-2409

CAN-2409, Candel's most advanced oncolytic viral immunotherapy product candidate, is a replication-deficient adenoviral gene construct encoding the herpes simplex virus thymidine kinase (HSV-tk) gene. HSV-tk is an enzyme that locally converts orally administered valacyclovir into a toxic metabolite that kills nearby cancer cells. Intra-tumoral administration results in immunogenic cell death, followed by the release of tumor-specific neoantigens in the tumor microenvironment. At the same time, the adenoviral vector elicits a strong pro-inflammatory signal to the tumor microenvironment, creating the optimal conditions to induce a specific CD8+ cytotoxic T cell-mediated immune response against the injected tumor and the uninjected distant metastases. This dual mechanism of antigen unmasking and immune activation may enable CAN-2409 to generate a powerful and lasting attack against a variety of the patient's tumor-associated neoantigens, minimizing the possibility for immune escape and development of tolerance.

Because of its versatility, CAN-2409 may have the potential to treat a broad range of solid tumors. Encouraging activity has been shown in several preclinical and clinical settings as monotherapy as well as in in combination with standard of care radiation therapy, surgery, chemotherapy, and immune checkpoint inhibitor treatment. Furthermore, more than 700 patients have been dosed to date with a favorable safety profile, 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 high-grade glioma, non-small cell lung cancer, pancreatic cancer, and 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 and 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. CAN-2409 is the lead product candidate from the adenovirus platform and CAN-3110 is the lead product candidate from the HSV platform. New discovery programs are based on the HSV platform.

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, statements CAN-2409's potential effects on tumor-associated neoantigens and on disease outcome in patients with prostate cancer, and planned regulatory interactions regarding CAN-2409. Any express or implied statements

that are not statements of historical fact may be deemed to be forward-looking statements. 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 our development programs; our expectations regarding the therapeutic benefit of our programs; our ability to efficiently discover and develop product candidates; our ability to obtain and maintain regulatory approval of our product candidates; the implementation of our business model, our ability to maintain our intellectual property, and strategic plans for our business and product candidates, and other risks identified in our SEC filings, including our Registration Statement on Form S-1, and subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim 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 our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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