# Candel Therapeutics Announces Patient-Reported Tolerability Data of Intraprostatic Injections in Ongoing Phase 3 Clinical Trial of CAN-2409 in Patients with Localized Prostate Cancer

Oct 28, 2021

NEEDHAM, Mass., Oct. 28, 2021 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Nasdaq: CADL), a late clinical stage biopharmaceutical company developing novel oncolytic viral immunotherapies, today announced that data on patient-reported tolerability assessment of intraprostatic injections will be presented in a virtual poster session at the 28th Annual Prostate Cancer Foundation Scientific Retreat.

- **Date:** Thursday, October 28, 2021
- **Presenter:** Laura K. Aguilar, MD, PhD, Chief Medical Officer at Candel Therapeutics, Inc.
- **Presentation Title:** Patient experience with intraprostatic injection of CAN-2409 or placebo followed by valacyclovir in a phase 3 clinical trial for localized prostate cancer in combination with standard of care radiation therapy with or without androgen suppression.

The data were generated from the company's ongoing phase 3 clinical trial, which is evaluating safety and efficacy of intra-prostatic injection with CAN-2409 or placebo followed by oral valacyclovir prodrug in combination with standard of care (radiation therapy ± short-term androgen deprivation therapy) in patients with localized prostate cancer having intermediate-risk or a single NCCN high-risk factor.

Clinical trial enrollment has been completed with a diverse population of 745 patients from 51 sites in the U.S. More than 2,000 injection procedures have been performed (40% transperineal, 56% transrectal, 4% not reported). Information on the patient experience is being collected with a questionnaire, and data is available from 32 patients who completed the questionnaire within 3 months of completing treatment. For the transperineal procedure, 65% of patients reported the intra-prostatic injections to be "the same or better" tolerated than a prostate biopsy, 30% "a little harder" to tolerate and 4% "much harder" to tolerate than a biopsy. For the transrectal procedure, 89% of patients reported the injections to be "the same or better" tolerated than a biopsy and 11% "a little harder" to tolerate than a biopsy. All patients (100%) reported overall feeling positive about their involvement in the study.

"These data further support the tolerability and patient receptiveness of intra-prostatic injection of CAN-2409 and its comparability to routine biopsies being performed in this patient population," said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel Therapeutics. "Listening to patients is important as we look towards the commercialization of CAN-2409, if approved. We believe CAN-2409 holds great promise as a treatment for patients with localized, non-metastatic prostate cancer, which may improve disease outcome, while eliminating the need for long-term androgen deprivation therapy and its associated side effects."

Details from the presentations will be available on the Candel website at https://www.candeltx.com/news/.

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

**About the Phase 3 Clinical Trial in Prostate Cancer**

The pivotal phase 3 study of CAN-2409 immunotherapy in patients with intermediate-high risk localized prostate cancer is a

placebo-controlled, randomized clinical trial to evaluate CAN-2409 treatment in combination with valacyclovir added to standard of care (radiation therapy ± short-term androgen deprivation therapy). 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.

**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. 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, 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 Registration Statement on Form S-1, the Company's Quarterly Report on Form 10-Q to be filed on or about the date of this press release, 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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