Candel Therapeutics Receives FDA Regenerative Medicine Advanced Therapy Designation for CAN-2409 for the Treatment of Prostate Cancer

May 28, 2025

NEEDHAM, Mass., May 28, 2025 (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 that the U.S. Food and Drug Administration (FDA) has granted Regenerative Medicine Advanced Therapy (RMAT) designation to CAN-2409 *(aglatimagene besadenovec)*, the Company's biological immunotherapy lead candidate, for the treatment of newly diagnosed localized prostate cancer in patients with intermediate-to-high-risk disease. CAN-2409 was also previously granted FDA Fast Track designation for the same indication.

The FDA's RMAT designation is intended to expedite the development and review of regenerative medicine therapies intended to treat, modify, reverse, or cure serious or life-threatening diseases where preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. The designation provides opportunities for intensive FDA guidance and organizational commitment to potentially support and expedite drug development. The designation also offers eligibility for mechanisms designed to speed Biologics License Application (BLA) review and approval, with potential opportunities for rolling review and priority review.

The RMAT designation was granted on the basis of the positive data from Candel's phase 3 randomized, placebo-controlled clinical trial evaluating the efficacy and safety of CAN-2409 plus valacyclovir (prodrug), together with standard of care (SoC) external beam radiation therapy, in newly diagnosed, localized, intermediate-to-high-risk prostate cancer.

Data announced by Candel in December 2024 showed that the phase 3 trial met its primary endpoint and demonstrated statistically significant improvement in disease-free survival (DFS) (p=0.0155) with a 30% reduction (HR 0.70) in the risk for prostate cancer recurrence or death due to any cause in patients who received CAN-2409 plus prodrug, combined with SoC radiotherapy (n=496), compared with patients who received placebo combined with SoC radiotherapy (n=249). CAN-2409 improved prostate-specific DFS with a 38% risk reduction compared with placebo (HR 0.62; p=0.0046). There was also a significant increase in the proportion of patients achieving a prostate-specific antigen (PSA) nadir of <0.2 ng/ml in the CAN-2409 treatment arm compared to the placebo arm (67.1% vs. 58.6%, respectively; p=0.0164). Furthermore, the data showed an 80.4% pathological complete response in the 2-year post-treatment biopsies after CAN-2409 administration compared to 63.6% in the control arm (p=0.0015). The safety profile of CAN-2409 was generally consistent with previous studies, with no new safety signals identified. Key aspects of the study design, including the primary endpoint, were agreed with the FDA under a Special Protocol Assessment (SPA).

"Receiving the FDA's RMAT designation underscores the critical unmet need in patients with early, localized prostate cancer and validates the promising clinical activity observed with CAN-2409. This designation further supports the design of our phase 3 study, including the DFS primary endpoint agreed upon with the FDA during the SPA negotiation," stated Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel.

Dr. Tak continued, "We look forward to collaborating with the FDA to pursue an expeditious approval of CAN-2409 once we submit our BLA—currently anticipated at the end of 2026. Our aim is to introduce a new treatment option for patients at the early stages of prostate cancer, a disease that has seen minimal innovation over the past two decades. We expect the RMAT designation to facilitate the BLA filing process and bring us closer to achieve this objective."

About CAN-2409

CAN-2409 (aglatimagene besadenovec), 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. HSV-tk is an enzyme that locally converts orally administered valacyclovir into a nucleotide analog 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 immunization against a variety of tumor antigens. Because of its mechanism of action, CAN-2409 has pan solid tumor treatment potential. Encouraging monotherapy activity as well as combination therapy activity with standard of care radiotherapy, surgery, chemotherapy, and immune checkpoint inhibitor (ICI) treatment, have previously been shown in several preclinical and clinical settings. More than 1,000 patients have been dosed with CAN-2409 with a favorable tolerability profile to date, supporting the potential for combination with standard of care, when indicated.

Candel has recently completed a successful phase 3 clinical trial of CAN-2409 in localized prostate cancer and positive phase 2a

clinical trials of CAN-2409 in non-small cell lung cancer (NSCLC) and borderline resectable pancreatic ductal adenocarcinoma (PDAC). CAN-2409 plus prodrug (valacyclovir) has been granted Fast Track Designation by the FDA for the treatment of PDAC, stage III/IV NSCLC in patients 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, and localized primary prostate cancer. CAN-2409, plus prodrug, has also been granted Regenerative Medicine Advanced Therapy (RMAT) designation by the FDA for the treatment of newly diagnosed localized prostate cancer in patients with intermediate-to-high-risk disease. Candel's pivotal phase 3 clinical trial in prostate cancer was conducted under a SPA agreed with the FDA. The FDA has also granted Orphan Drug Designation to CAN-2409 for the treatment of PDAC.

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-2409 is the lead product candidate from the adenovirus platform; CAN-3110 is the lead product candidate from the HSV platform and is currently in an ongoing phase 1b clinical trial in recurrent high-grade glioma. Finally, 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

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 and key data readout milestones and presentations; expectations regarding the submission of the BLA for CAN-2409 in intermediate-to-high-risk localized prostate cancer; expectations regarding early biological readouts as predictor of clinical response; expectations regarding the therapeutic benefit of the Company's platforms, including the ability of its platforms to improve overall survival and/or disease-free survival of patients living with difficult to treat, solid tumors; and expectations regarding the potential benefits conferred by RMAT designation. 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; that final data from the Company's preclinical studies and completed clinical trials may differ materially from reported interim data from ongoing studies and trials; 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, including strategic plans for the Company's business and product candidates; and other risks identified in the Company's filings with the U.S. Securities and Exchange Commission (SEC), including the Company's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, each as filed with the SEC and any 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.

Investor Contact:
Theodore Jenkins
VP, Investor Relations and Business Development
Candel Therapeutics, Inc.
tjenkins@candeltx.com

Media Contact:
Ben Shannon
ICR Healthcare
CandelPR@westwicke.com