Candel Therapeutics Presents Phase 3 Clinical Trial of CAN-2409 in Localized Prostate Cancer at ASTRO 2025

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- *CAN-2409 improved disease-free survival in patients with intermediate-to-high-risk, localized prostate cancer compared to placebo in patients treated with either conventional or moderate hypofractionated radiotherapy with curative intent, independent of the specific modality of radiation therapy used*

NEEDHAM, Mass., Sept. 29, 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, presented subgroup analyses focused on the radiation regimen from the Company's positive phase 3 clinical trial of CAN-2409 (aglatimagene besadenovec) in patients with intermediate-to-high-risk localized prostate cancer at the 2025 Annual Meeting of the American Society for Radiation Oncology (ASTRO).

Current standard-of-care radiation therapy for intermediate-to-high-risk localized prostate cancer has remained largely unchanged, with a significant unmet medical need, as approximately ~30% of patients experience disease recurrence within 10 years.

The Company has previously presented data from a randomized phase 3 clinical trial of CAN-2409 plus valacyclovir vs. placebo added to standard of care radiotherapy with curative intent in patients with localized prostate cancer. The press release is posted on the investor relations section of our website, available here. The randomized, double-blind, placebo-controlled, multicenter phase 3 trial (NCT01436968) enrolled 745 patients with intermediate-to-high-risk localized prostate cancer randomized 2:1 to either CAN-2409 plus valacyclovir in combination with standard of care or standard of care alone, with experimental treatment administered before and during radiation therapy. The trial achieved its primary endpoint with a 30% improvement in disease-free survival (HR 0.7, p=0.0155) and demonstrated a 38% improvement in prostate cancer-specific disease-free survival (HR 0.62, p=0.0046). At two years, pathological complete response rates were 80.4% as compared to 63.6% observed in the control arm (p=0.0015).

This study represents the first potential advancement in localized, non-metastatic prostate cancer in more than 20 years. The Company today released additional information from its subgroup analysis of the phase 3 data showing that CAN-2409's activity was independent of the radiation modality used in the trial.

Key Highlights from ASTRO 2025 Presentation:

- CAN-2409 significantly improved prostate cancer-specific outcomes (HR 0.62; p=0.0046). Effects observed in both moderate hypofractionated EBRT (HR 0.52, CI 0.30 – 0.93, p=0.0236) and conventional EBRT (HR 0.76, CI 0.53 – 1.07, p=0.1131)
- Demonstrated safety and compatibility across radiation therapy modalities, with both conventional radiation therapy (~78 Gy in 2 Gy fractions, ~72% of patients) and moderate hypofractionated radiation therapy (60 Gy in 3 Gy fractions, ~25% of patients) showing similar tolerability profiles
- Grade ≥ 3 treatment related adverse events were similar in the CAN-2409 plus valacyclovir and control arms with both hypofractionated (1.6% vs. 1.9%) and standard EBRT (1.8% vs. 1.1%), respectively

"These additional analyses suggest that the efficacy of CAN-2409 is independent of the modality of radiation used. Most importantly, the activity of CAN-2409 was maintained with moderate hypofractionated radiation, which is more convenient for patients," said Glen Gejerman, M.D., M.B.A., Co-Director of Urologic Oncology at Hackensack Meridian Health and one of the principal investigators of the study.

Paul Peter Tak, M.D., Ph.D., FMedSci, President and Chief Executive Officer of Candel said, "These new insights presented at ASTRO further support the broad therapeutic potential of CAN-2409 in localized prostate cancer treated with curative intent. Previously, we have shown the benefit of CAN-2409 compared to placebo in patients treated with standard of care radiotherapy, independent of the use of short-term androgen deprivation therapy. The consistency of benefit, across radiation therapy modalities, supports the therapy's potential as the first major advancement in localized prostate cancer treatment in over 20 years. Our regulatory strategy remains on track with Biologics License Application submission expected in the fourth quarter of 2026."

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 tumor. After intratumoral administration, HSV-tk enzyme activity results in conversion of prodrug (valacyclovir) into deoxyribonucleic acid (DNA)-incorporating nucleotide analogs, leading to immunogenic cell death in cells exhibiting DNA damage and proliferating cells, with subsequent release of a variety of tumor (neo)antigens in the tumor microenvironment. At the same time, the adenoviral serotype 5 capsid proteins promote inflammation through the induction of expression of pro-inflammatory cytokines, chemokines, and adhesion molecules. 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. 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. More than 1,000 patients have been dosed with CAN-2409 in clinical trials with a favorable tolerability profile to date, supporting the potential for combination with standard of care, when indicated.

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 herpes simplex virus (HSV) gene constructs, respectively. CAN-2409 is the lead product candidate from the adenovirus platform. The Company recently completed successful phase 2a clinical trials of CAN-2409 in non-small cell lung cancer (NSCLC) and pancreatic ductal adenocarcinoma (PDAC), and a pivotal, placebo-controlled, phase 3 clinical trial of CAN-2409 in localized prostate cancer, conducted under a Special Protocol Assessment agreed with the U.S. Food and Drug Administration (FDA). The FDA also granted Regenerative Medicine Advanced Therapy Designation to CAN-2409 for the treatment of newly diagnosed localized prostate cancer in patients with intermediate-to-high-risk disease, Fast Track Designation in NSCLC and prostate cancer, and both Fast Track Designation and Orphan Drug Designation to CAN-2409 for the treatment of PDAC.

CAN-3110 (linoserpaturev) is the lead product candidate from the HSV platform and is currently in an ongoing phase 1b clinical trial in recurrent high-grade glioma. Initial results were published in *Nature* and CAN-3110 received Fast Track Designation and Orphan Drug Designation from the FDA. 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; 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 intermediate-to-high-risk localized prostate cancer; expectations regarding early biological readouts as predictor of clinical response; expectations regarding the submission of the Biologics License Application for CAN-2409 in intermediate-to-high-risk localized prostate cancer; and expectations regarding the potential benefits conferred by regulatory designations. 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 June 30, 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.

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