Candel Therapeutics Announces Publication in The Lancet Oncology of Pivotal Phase 3 Data Demonstrating Significant Improvement in Disease-Free Survival with Aglatimagene Besadenovec (CAN-2409) in Localized Prostate Cancer

Jun 2, 2026

- *Peer reviewed publication details pivotal data, demonstrating 30% improvement in disease-free survival (DFS) in patients with localized prostate cancer undergoing standard-of-care radiotherapy with curative intent combined with aglatimagene besadenovec (aglatimagene) plus valacyclovir compared to placebo plus valacyclovir*
- *Findings support that addition of aglatimagene to standard-of-care radiotherapy can provide a meaningful benefit without increasing clinically significant toxicity*
- *Data reported in this publication will support planned Biologics License Application (BLA) submission for aglatimagene in fourth quarter of 2026*

NEEDHAM, Mass., June 02, 2026 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a clinical-stage biopharmaceutical company focused on developing multimodal immunotherapies to improve disease outcomes for patients with cancer, today announced the publication of results from the Company's randomized, double-blind, placebo-controlled, multicenter pivotal phase 3 clinical trial of aglatimagene in patients with intermediate- to high-risk localized prostate cancer, which the Company first announced in December 2024, in *The Lancet Oncology,* one of the world's leading peer-reviewed oncology journals (impact factor 35.9).

"Localized prostate cancer remains an area of significant unmet need, with many patients experiencing disease recurrence after definitive radiotherapy. Innovation in this setting has been limited over the past two decades, making these peer-reviewed data particularly important for patients with intermediate- to high-risk localized prostate cancer," said Dr. Mark Garzotto, Professor of Urology and Radiation Medicine, School of Medicine, Oregon Health & Science University, and Chief of Urology at the Portland VA Medical Center. "The publication of these findings in *The Lancet Oncology* provides important peer-reviewed validation of the clinical significance of the results observed with aglatimagene in combination with radiotherapy."

The manuscript, titled "Aglatimagene besadenovec (CAN-2409) with radiotherapy for patients with localized prostate cancer: a phase 3, multicentre, randomised, double-blind, placebo-controlled trial," reports results from a pivotal phase 3 clinical trial (NCT01436968) evaluating aglatimagene plus valacyclovir in combination with standard-of-care radiotherapy administered with curative intent. The trial enrolled 745 patients and met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in DFS compared with radiotherapy alone.

The publication reports:

- 30% improvement in DFS in the aglatimagene arm, compared to placebo (hazard ratio 0.70; 95% confidence interval (CI) 0.52-0.94; p=0.016)
- 38% improvement in prostate cancer-specific DFS (prostate cancer recurrence or prostate cancer related death) (hazard ratio 0.62; 95% confidence interval 0.44-0.87; p=0.0046)
- Aglatimagene improved pathological complete response rate in a post-hoc blinded review of biopsies collected two years after completion of radiotherapy, with 80% (167/209) of patients in the aglatimagene treatment arm observed with negative biopsies, versus 63% (62/98) observed in the placebo group (p=0.0018)
- A generally favorable safety profile, with the most common treatment-related adverse events (chills, flu-like symptoms, fatigue, pyrexia, pollakiuria, and nausea) observed to be grades 1-2 and self-limited
- While the study was not statistically powered to establish benefit in subgroups, exploratory descriptive analyses suggested clinical benefit of aglatimagene compared to placebo, independent of radiation therapy regimen and independent of androgen deprivation therapy use

The Company recently presented extended follow-up data from this phase 3 trial at the American Urological Association 2026 Annual Meeting, showing a 39% improvement in prostate cancer-specific DFS after an additional 20 months of follow-up (updated median follow-up, as of March 15, 2026, was 58 months). These data also showed consistently favorable trends across secondary and exploratory endpoints, including, time to biochemical failure, time to and incidence of metastasis, and time to salvage

anti-cancer treatment in the aglatimagene arm compared with the placebo arm.

"The statistically significant increase in pathological complete response rates — observed in prostate biopsies obtained approximately two years after aglatimagene treatment and reported today in *The Lancet Oncology* — is particularly meaningful because biopsy findings after radiotherapy have previously been shown to predict later biochemical failure and metastasis with longer follow-up," said Garrett Nichols, M.D., Chief Medical Officer of Candel. "Together, these data strengthen our confidence that earlier tumor control, reflected in biopsy-based DFS events, may translate into durable and clinically meaningful benefit for patients."

"The publication of this pivotal phase 3 trial in *The Lancet Oncology* provides important peer-reviewed validation of the significance of these findings for patients with localized prostate cancer," said Paul Peter Tak, M.D., Ph.D., FMedSci, President and Chief Executive Officer of Candel. "Patients who elect to undergo radical treatment for localized prostate cancer do so with the goal of increasing their chance of living free from cancer while reducing the risk of recurrence and the need for future anti-cancer therapies that may carry additional toxicity and affect quality of life. These data showed a clinically meaningful reduction in disease recurrence in patients treated with aglatimagene in combination with radiotherapy. The primary endpoint findings were supported by sensitivity analyses and reinforced by secondary and exploratory endpoints and together provide a comprehensive and internally consistent body of evidence that supports the therapeutic potential of aglatimagene in localized prostate cancer."

The published manuscript is available online at The Lancet Oncology

About aglatimagene besadenovec (CAN-2409)

Aglatimagene, 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. Aglatimagene 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 aglatimagene in clinical trials with a favorable tolerability profile to date, supporting the potential for use with standard of care, when indicated. Aglatimagene is currently not approved by the U.S. Food and Drug Administration or any other regulatory authority for any use.

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

Linoserpaturev (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, evaluating the effects of repeat linoserpaturev injections. Initial results were published in *Nature* and *Science Translational Medicine* and linoserpaturev 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 submission of the BLA for aglatimagene 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; expectations regarding the potential benefits conferred by regulatory designations; and expectations regarding the potential benefits conferred by the publication of the Company's findings in *The Lancet Oncology*. 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; the impact of the Company’s existing and any future indebtedness on its ability to operate its business; the Company’s ability to access any future tranches under its debt facility and to comply with all of its obligations thereunder; 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, 2026, 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
Vice President, Investor Relations, and Business Development
Candel Therapeutics, Inc.
tjenkins@candeltx.com

Media Contact
Ben Shannon
ICR Healthcare
CandelPR@icrhealthcare.com