Candel Therapeutics Reports Extended Clinical Benefit Over Multiple Clinical Endpoints in Patients from Phase 3 Trial of Aglatimagene Besadenovec (CAN-2409) in Localized Prostate Cancer Under Prolonged Follow-up at AUA 2026 Annual Meeting

May 15, 2026

- *Extended follow-up data from the phase 3 study (20 months after reported topline data, median follow-up 58 months) confirmed a statistically significant and clinically meaningful improvement in prostate cancer–specific disease-free survival (DFS) of 39% after aglatimagene administration compared to placebo, reinforcing the potential of aglatimagene to reduce the risk of tumor recurrence in men receiving radiotherapy for localized disease.*
- *Clinical benefit demonstrated in the intention-to treat (ITT) population by secondary and clinically relevant exploratory endpoints with numerical improvements observed in time to biochemical failure (TTBF), lower incidence of and increased time to metastases, and increased time to salvage anti-cancer treatment (TTNT)*
- *Exploratory analysis within the sub-group of patients with intermediate-risk prostate cancer (85% of the study population) suggested that treatment with aglatimagene plus radiotherapy resulted in a statistically significant 90% reduction in time to metastasis (TTM) versus placebo plus standard-of-care radiotherapy, along with a lower metastasis rate, supporting the potential of aglatimagene to control both local and systemic disease recurrence*

NEEDHAM, Mass., May 15, 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 new results from extended follow-up of its randomized, double-blind, placebo-controlled pivotal phase 3 trial of aglatimagene besadenovec (aglatimagene or CAN-2409) in intermediate- to high-risk localized prostate cancer. These findings demonstrate consistent clinical benefit across multiple exploratory endpoints, reinforcing the positive topline data announced in December 2024 after an additional 20 months of follow-up, with a cutoff date of March 15, 2026.

The data were presented by Mark G. Garzotto, M.D., Professor of Urology and Radiation Medicine at Oregon Health & Science University, during the “Practice-changing, Paradigm-shifting Clinical Trials in Urology” oral plenary session at the American Urological Association (AUA) 2026 Annual Meeting in Washington, D.C.

Key Highlights from AUA 2026 Presentation:

Among the 745 patients enrolled in the randomized, double-blind, placebo-controlled trial, the aglatimagene arm exhibited a 39% improvement in prostate cancer-specific disease-free survival (PCa-specific DFS) compared to placebo (hazard ratio [HR] 0.61; 95% confidence interval [CI]: 0.44, 0.85; p=0.0031) after a median follow-up of 58 months (data as of March 15, 2026). Two prostate cancer-specific deaths occurred (1 in each arm) after median follow-up of less than 10 years.

We observed consistently favorable trends in the ITT population across all secondary and exploratory endpoints, including time to biochemical failure (TTBF; HR 0.72, CI 0.40,1.31), time to metastasis (TTM; HR 0.58, CI 0.21, 1.59), rate of metastasis [(1.6% (8/496) vs. 2.8% (7/249)], and time to salvage anti-cancer therapy (time to new treatment (TTNT) HR 0.72, CI 0.39, 1.31), when comparing the aglatimagene arm with placebo on top of standard-of-care radiotherapy.

Within the intermediate-risk subgroup (635 patients, 85% of the ITT population), the aglatimagene arm demonstrated 41% improvement in PCa-specific DFS (HR 0.59, 95% CI 0.41, 0.84, p=0.0034) relative to placebo. In addition, descriptive analyses showed 52% improvement in TTBF (HR 0.48, CI 0.22, 1.03), 90% improvement in TTM (HR 0.1, CI 0.01, 0.85), lower rate of metastatic disease [0.24% (1/422) vs. 2.35% (5/213)], and 49% improvement in TTNT (HR 0.51, CI 0.24, 1.1), when comparing the aglatimagene arm with the placebo arm.

In December 2024, we reported that aglatimagene significantly improved the rate of pathological complete response in 2-year biopsies compared with placebo, suggesting the cancer had been eradicated at a microscopic level.[1] Previously published work has shown that histologic changes precede clinical evidence of recurrence and that prostate biopsies, positive for cancer cells ≥ 2 years after radiotherapy, are predictive of subsequent clinically meaningful outcomes, including biochemical failure and development of metastases.[2] While the number of events for biochemical failure and development of metastases presented at AUA is, as expected, still too small to achieve statistical significance for most outcomes, the observed trends are consistent and in line with this published literature, supporting the potentially long-term clinical benefit of aglatimagene. We will continue to monitor the patients over time.

“After prolonged follow-up, these data further demonstrated that aglatimagene delivered a statistically significant and clinically meaningful improvement in prostate cancer–specific disease-free survival, with a 39% reduction in the risk of recurrence,” said Paul Peter Tak, M.D., Ph.D., FMedSci, President and Chief Executive Officer of Candel Therapeutics. “Importantly, we are seeing consistent, favorable trends across multiple clinically relevant secondary and exploratory endpoints, including time to biochemical failure, time to metastasis, and need for subsequent anti-cancer therapy. These findings, combined with earlier evidence of increased pathological complete response at two years, reinforce our confidence that aglatimagene has the potential to deliver durable control of both local and systemic disease and to meaningfully reduce the risk of recurrence for patients undergoing radiotherapy with curative intent for localized prostate cancer. We will continue to follow patients as these data mature, with the expectation that the long-term clinical benefit may become even more apparent over time.”

“I am grateful for the opportunity to have presented these data at the AUA Annual Meeting on behalf of all of our study investigators,” said Mark G. Garzotto, M.D. “What is particularly compelling is the clear translation of biologic activity into meaningful clinical benefit: patients are experiencing longer periods free from recurrence and the need for additional therapy. These results move us closer to what matters most to patients—living free from cancer—and underscore the potential o aglatimagene to potentially redefine the standard-of-care in localized prostate cancer.”

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. If approved, aglatimagene immunotherapy could represent the first new therapy for men with localized prostate cancer in over 20 years. Candel continues to plan to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration in the fourth quarter of 2026. Details from the presentation are available on the Candel website at https://www.candeltx.com/media/.

Conference Call and Webcast Replay:

Candel hosted a webcast and conference call on Friday, May 15, 2026, which discussed the Company’s extended follow-up data from the phase 3 clinical trial of aglatimagene in patients with intermediate- to high-risk localized prostate cancer.

The replay of the webcast can be accessed here and on the Candel website at https://candeltx.com under Events & Presentations, in the Investors section of the website.

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 besadenovec (aglatimagene or CAN-2409) 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, 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 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; 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.

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[1] DeWeese TL et al. Lancet Oncology [in press]
[2] Singh S et al. Prostate Cancer Prostatic Dis 2021;24:612-622