



Candel Therapeutics Announces Integrated Clinical and Biomarker Data That Showed Durable Local and Systemic Immune Activation after Aglatimagene Besadenovec in Intermediate-Risk Localized Prostate Cancer

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- *Novel systemic immune data demonstrated T-cell activation following local administration of aglatimagene. Together with recently disclosed evidence of persistent local immune remodeling, these findings provide mechanistic support for the long-term clinical outcomes, including disease-free survival and prolonged time to biochemical failure, time to metastasis, and time to salvage anti-cancer therapy, observed in this patient population*
- *Biodistribution and shedding data from the PrTK05 phase 2 trial remain on track for inclusion in the planned Q4 2026 Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA) for localized prostate cancer*

NEEEDHAM, Mass., Sept. 30, 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 novel immunological biomarker data from the ongoing phase 2 PrTK05 trial ([NCT07332000](#)) in patients with intermediate-risk localized prostate cancer. These data, together with histologic and clinical data from the intermediate-risk prostate cancer subgroup of the PrTK03 phase 3 trial ([NCT01436968](#)) (635 patients, 85% of the intention-to-treat population), are expected to be presented at a future scientific meeting. Intermediate-risk prostate cancer represents the largest group of patients with localized disease treated with curative-intent external beam radiation therapy (EBRT), accounting for approximately 65,000 patients annually in the United States. Despite radiotherapy, disease recurrence, local and metastatic progression, and the need for salvage anti-cancer therapies that can be associated with substantial toxicity and impaired quality of life remain important unmet needs. This underscores the need for new treatments designed to enhance local tumor control and reduce the risk of disease progression.

PrTK03 Clinical Outcomes

With follow-up through March 15, 2026 (median, 58.0 months), the phase 3 trial showed that patients with intermediate-risk disease (635 patients) treated with aglatimagene plus EBRT experienced a 41% reduction in the risk of prostate cancer recurrence or prostate cancer-specific death versus placebo plus EBRT (HR 0.59; 95% CI 0.41–0.84; $p=0.0034$).

Additional exploratory, descriptive analyses showed 52% improvement in the time to biochemical failure (HR 0.48; 95% CI 0.22–1.03), a 90% improvement in the time to metastasis (HR=0.10; 95% CI 0.01–0.85), and a 49% reduction in the time to salvage anticancer therapy (HR 0.51; 95% CI 0.24–1.10).

PrTK03 Pathologic and Biomarker Data

Centrally reviewed biopsies from patients with intermediate-risk disease obtained 22–26 months after treatment demonstrated a substantial improvement in rate of negative biopsies, defined as the absence of tumor cells in a standard-of-care diagnostic prostate biopsy. Among 277 evaluable patients with intermediate-risk disease:

- 76.6% (144/188) in the aglatimagene arm had negative biopsies versus 60.7% (54/89) in the control arm
- Positive biopsies were observed in 20.7% of the aglatimagene arm and 38.2% of the control arm (stratified CMH $p = 0.0034$; chi-square $p = 0.0026$). Six undetermined biopsies were included in the total number of biopsies analyzed and are part of the denominator.

Building on the AI-enabled histologic analysis presented at ASTRO, exploratory digital pathology analyses showed:

- Increased lymphocytic infiltration after treatment in both arms ($p<0.001$)
- In paired biopsies with detectable post-treatment tumor ($n=98$), aglatimagene increased the intratumoral lymphocyte fraction ($p=0.002$) and lymphocyte–tumor enrichment and mixing scores (both $p<0.001$)

These immune changes were observed more than two years after treatment.

PrTK05 Systemic Immune Response Data

Early data from the PrTK05 flow-cytometry analyses provided evidence that local treatment with aglatimagene is associated with systemic expansion and activation of multiple circulating cytotoxic T-cell populations. Serial blood samples from 13 patients with intermediate-risk prostate cancer, treated with aglatimagene plus standard-of-care (SoC) EBRT, and 6 patients receiving SoC alone showed expansion of CD8-positive effector and effector-memory T cell populations in the aglatimagene arm, alongside expansion of Ki67-positive proliferating and granzyme B-positive cytotoxic CD8-positive T-cells. These longitudinal findings extend the local PrTK03 tissue observations by suggesting a coordinated systemic immune response beyond the locally treated prostate; formal comparison with SoC-treated controls is ongoing.

Together, these analyses provide complementary evidence of durable local tumor clearance and immune remodeling within the prostate, along with systemic expansion and activation of cytotoxic T-cell populations beyond the treated tumor.

“This signature of coordinated immune activation across tissue and blood in prostate cancer is consistent with findings previously observed following aglatimagene treatment in other solid tumor indications, including NSCLC and high-grade glioma,” said Francesca Barone, M.D., Ph.D., Chief Scientific Officer of Candel Therapeutics. “These findings are consistent with a shared mechanism across solid tumors involving immunogenic tumor cell death followed by individualized local and systemic anti-tumor immunity that does not depend on a predefined antigen or biomarker.”

Paul Peter Tak, M.D., Ph.D., FMedSci, President and Chief Executive Officer of Candel Therapeutics, added, “The evidence of systemic immune activation in intermediate-risk prostate cancer strengthens the biological rationale for evaluating aglatimagene in metastatic solid tumor settings where systemic disease control is critical. These findings underscore the broader potential of our multimodal immunotherapy platform.”

The biodistribution and shedding data from the phase 2 PrTK05 trial have been compiled for inclusion in Candel's BLA for aglatimagene in localized prostate cancer, which the Company plans to submit to the FDA in Q4 2026. The Company intends to submit the data for presentation at an upcoming scientific conference and for potential publication in a peer-reviewed journal in 2027.

About aglatimagene besadenovec

Aglatimagene besadenovec (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 nonclinical 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 FDA 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) is the lead product candidate from the adenovirus platform. The Company 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 FDA and published in [The Lancet Oncology](#). 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.

Linoserparev 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 linoserparev injections. Initial results were published in [Nature](#) and [Science Translational Medicine](#) and linoserparev 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 expectations regarding planned BLA submission and potential commercial readiness; 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 nonclinical 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 any subsequent Quarterly Reports on Form 10-Q, 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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