



Candel Therapeutics Announces New Data Showing Sustained Immune Remodeling More Than Two Years After Aglatimagene Besadenovec Treatment in Localized Prostate Cancer at ASTRO 2026

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- *AI-enabled digital pathology analysis shows aglatimagene significantly increased lymphocyte infiltration and immune engagement with tumor cells compared to standard-of-care radiotherapy alone two years after treatment*

NEEDHAM, 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 the presentation of new biomarker data from its completed phase 3 clinical trial of aglatimagene besadenovec (aglatimagene) in patients with localized intermediate- to high-risk prostate cancer at the American Society for Radiation Oncology (ASTRO) Annual Meeting 2026.

The Company used digitized hematoxylin and eosin-stained prostate biopsy samples collected at baseline and after treatment with either aglatimagene or placebo, from patients who had completed the 3-injection course (n=647) in the randomized, placebo-controlled phase 3 study ([NCT01436968](#)). AI-enabled digital pathology analysis performed on tumor biopsies evaluable for digital analysis (622 pre-treatment and 427 post-treatment collected more than two years after completion of radiation), demonstrates that aglatimagene plus external beam radiation therapy (EBRT) significantly increased intratumoral lymphocyte infiltration and remodeled the tumor microenvironment compared with placebo plus EBRT. Among those patients with residual tumor, aglatimagene increased lymphocyte infiltration within tumor regions and enhanced lymphocyte-tumor engagement.

Key Highlights from ASTRO 2026 Presentation:

- The Company previously reported that two years after treatment, 80% of evaluable aglatimagene patients (n=167) had negative prostate biopsies versus 63% of control patients (n=62) (p=0.0018)
- Aglatimagene significantly increased overall lymphocytic fraction compared to control (p=0.048), with both arms showing immune activation from radiation therapy (p<0.001) (calculated in all digital-pathology evaluable biopsies; 622 pre-treatment biopsies and 427 post-treatment biopsies analyzed)
- In paired biopsies from patients with residual tumor (n=108; aglatimagene n=62, control n=46), aglatimagene significantly increased intratumoral lymphocyte fraction (p=0.006), lymphocyte-tumor enrichment (p=0.003), and lymphocyte-tumor mixing (p<0.001)

"While radiation therapy alone drives immune infiltration into prostate tumors, these data support that aglatimagene produced a qualitatively distinct immune response," said Francesca Barone, M.D., Ph.D., Chief Scientific Officer of Candel Therapeutics. "The significantly greater lymphocyte infiltration and sustained lymphocyte-tumor engagement which we observed, more than two years after treatment, supports durable immune remodeling rather than transient inflammation. This mechanistic insight may help explain the clinical improvements in disease-free survival and pathologic outcomes we reported in the phase 3 trial."

"These tissue-level findings provide important biological support for the clinical benefit demonstrated in our phase 3 trial," said Paul Peter Tak, M.D., Ph.D., FMedSci, President and Chief Executive Officer of Candel. "We believe the convergence of sustained immune remodeling, improved pathologic response, and a clinically meaningful improvement in disease-free survival provides a compelling and coherent picture of aglatimagene's activity in localized prostate cancer as we advance toward our planned Biologics License Application submission."

The data was presented by Dr. Barone during the Genitourinary Cancer session at ASTRO 2026 on September 29, 2026, and the poster is titled "Quantitative digital pathology defines immune activation following aglatimagene besadenovec immunotherapy in localized prostate cancer" (Abstract LBA 30).

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

(valgancyclovir) 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 U.S. Food and Drug Administration (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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