Candel Therapeutics Presents SITC 2026 Data Highlighting Systemic Immune Activation and Survival Outcomes Across Clinical-Stage Portfolio

Nov 6, 2026

Three posters, including a late-breaking presentation, provide new clinical and biomarker data for aglatimagene besadenovec (aglatimagene) in localized prostate cancer and non-small cell lung cancer (NSCLC), and for linoserpaturev in recurrent glioblastoma

- *PrTK05 data show systemic cytotoxic T-cell activation following intraprostatic administration of aglatimagene in intermediate-risk localized prostate cancer, together with data consistent with transient biodistribution and shedding, supporting the planned BLA submission*
- *In progressive non-squamous NSCLC, longitudinal immune changes in blood and tumor tissue and specific multi-omic features were associated with survival beyond 24 months, supporting the biological rationale for the ongoing phase 3 AURORA trial*
- *Linoserpaturev data in recurrent glioblastoma showed durable survival in a subset of patients following treatment, alongside persistent tumor T-cell infiltration and exploratory immune changes that may inform strategies to further enhance and sustain antitumor activity*

NEEDHAM, Mass., Nov. 06, 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 clinical and biomarker data from three poster presentations at the Society for Immunotherapy of Cancer's (SITC) 41st Annual Meeting, taking place November 4—8, 2026, in Phoenix, Arizona.

Across the presentations, data from aglatimagene and linoserpaturev highlight systemic and tumor-localized immune effects, biomarker associations with longer survival, and updated survival outcomes across localized prostate cancer, NSCLC, and recurrent glioblastoma. Collectively, the findings inform Candel's planned biologics license application (BLA) for aglatimagene in localized prostate cancer, support the biological rationale for the ongoing phase 3 AURORA trial in metastatic non-squamous NSCLC, and guide the continued development of linoserpaturev in recurrent glioblastoma.

Aglatimagene in Localized Prostate Cancer (Phase 2)

PrTK05 is a phase 2 trial (NCT07332000) designed to characterize the immunologic effects, viral shedding, and biodistribution of aglatimagene plus standard-of-care (SoC) external beam radiation therapy (EBRT), with or without androgen deprivation therapy (ADT), compared with SoC EBRT, with or without ADT, in patients with localized intermediate-risk prostate cancer. At the data cutoff (October 16th), flow-cytometry analyses included up to 17 patients who received aglatimagene plus valacyclovir and SoC and up to seven patients in a concurrently enrolled SoC-only cohort. Peripheral blood samples were collected at baseline and after each injection through Weeks 16-18.

Key findings included:

- CD8+ cytotoxic T cells in peripheral blood increased at the 2-6-week assessments after the first injection ($p<0.05$), including central memory T cells (TCM; $p<0.05$) and effector memory T cells (TEM; $p<0.05$). These cell populations declined in the SoC-only group.
- Activated, proliferating CD8+ GZMB+ Ki67+ T cells increased sharply 2-3 weeks after the first injection ($p<0.0001$) and remained above baseline through Weeks 16-18. No increase was observed after SoC alone.
- Serum levels of granzyme A, granzyme B, and perforin increased 2-3 weeks after the first injection of aglatimagene ($p<0.05$).

Together, these results suggest systemic immune activation following intraprostatic administration of aglatimagene and are consistent with previous observations in glioblastoma, pancreatic cancer, and NSCLC.

PrTK05 data show transient detection of aglatimagene vector DNA in peripheral blood after intraprostatic administration of aglatimagene and clearance in urine samples at weeks 16-18. These findings are consistent with transient systemic biodistribution and shedding following administration.

"The PrTK05 findings show that adding aglatimagene to standard-of-care can generate a systemic cytotoxic T-cell response that was not observed with radiation-based standard of care alone," said Paul Peter Tak, M.D., Ph.D., FMedSci, President and Chief Executive Officer of Candel Therapeutics. "Together with biodistribution and shedding results that are consistent with our earlier studies, these data strengthen the mechanistic package we plan to include in the BLA submission for aglatimagene in localized prostate cancer."

Aglatimagene in Progressive NSCLC (Phase 2a)

The SITC presentation reports additional biomarker analyses from the phase 2a trial of aglatimagene in non-squamous NSCLC published in the *Journal for ImmunoTherapy of Cancer* on October 1, 2026.

The trial (NCT04495153) included 46 patients in the per-protocol population with stage III/IV NSCLC who had stable or progressive disease despite immune checkpoint inhibitor treatment. Median overall survival was 25.4 months; 23 patients (50%) were alive at 24 months, and six patients (13%) survived beyond 50 months.

New analyses presented at SITC showed that aglatimagene treatment was associated with:

- Longitudinal analyses demonstrated increases in T-cell repertoire diversity over time, consistent with broadening of the adaptive immune response.
- Post-treatment tumor biopsies demonstrated increased expression of genes associated with cytotoxic T-cell activation, consistent with enhanced local antitumor immune activity.
- Increases in CD40L, NCR1, CXCL5, and granzyme B levels were significantly associated with survival beyond 24 months.
- Abundant antigen-presenting cells and monocyte/macrophage-rich myeloid niches in tumor biopsies that were also associated with survival beyond 24 months.

"These multi-omic analyses connect longitudinal immune changes in blood and tumor tissue with clinical outcomes in patients whose disease had remained stable or progressed despite checkpoint inhibition," said Garrett Nichols, M.D., Chief Medical Officer of Candel Therapeutics. "Although these findings are associative, their consistency across complementary biomarker measures adds to the biological rationale for evaluating aglatimagene in the ongoing phase 3 AURORA trial in metastatic non-squamous NSCLC."

Linoserpaturev in Glioblastoma (Phase 1b)

Linoserpaturev is a first-in-class oncolytic herpes simplex virus-1 immunotherapy being evaluated in an ongoing phase 1b trial in recurrent high-grade glioma (rhGG), including glioblastoma (NCT03152318). The SITC poster reports updated overall survival from single- and repeat-administration cohorts.

- In Arms A+B, 50 patients received 51 intratumoral injections, including one patient who received two injections. Median overall survival was 12.0 months (95% CI, 8.3-14.4), with median follow-up of 68.6 months. Eleven of 50 patients (22%) were alive at 18 months, eight (16%) at 24 months, five (10%) at 36 months, and two (4%) at 48 months, as of the August 14, 2026 data cutoff.
- In Arm C, 12 patients with recurrent glioblastoma received up to six administrations of linoserpaturev. Median overall survival was 14.3 months (95% CI, 8.9 months-not reached), with median follow-up of 15.3 months. Five of 12 patients remained alive at the July 13, 2026 efficacy cutoff. These survival data remain immature, and six patients had only recently initiated treatment and therefore had limited follow-up at the cutoff.

The survival observed following single and repeated administration supports continued evaluation of linoserpaturev as a monotherapy in recurrent glioblastoma. Previously reported spatial profiling showed persistent CD4+ and CD8+ T-cell infiltration after linoserpaturev treatment and identified VEGFA-high hypoxic regions with relatively poor T-cell infiltration.

Based on that observation, an exploratory retrospective analysis evaluated overall survival among patients who received bevacizumab, an anti-VEGFA therapy, after linoserpaturev. Of 41 patients treated with a single linoserpaturev injection, 28 subsequently received bevacizumab. The analysis did not show a statistically significant overall survival improvement (p=0.7793), although a delayed initial decline in survival probability was observed among patients who received bevacizumab. Because bevacizumab use was not protocol defined and the analysis was retrospective and non-randomized, the findings do not establish treatment benefit. They provide a hypothesis-generating basis for prospective evaluation of treatment sequence and timing.

"The updated survival data following both single and repeated linoserpaturev administration are encouraging in a disease with persistently poor outcomes," said Francesca Barone, M.D., Ph.D., Chief Scientific Officer of Candel Therapeutics. "Importantly, the

tissue analyses are also helping us identify biologically grounded strategies that may further enhance and sustain antitumor activity. The bevacizumab analysis is exploratory and does not establish benefit, but it provides a clear hypothesis for prospective evaluation as we refine the development strategy for linoserpaturev in recurrent glioblastoma."

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. The Company completed successful phase 2a clinical trials of aglatimagene in non-small cell lung cancer (NSCLC) with results published in the *Journal for ImmunoTherapy of Cancer*, 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) 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. 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 linoserpaturev

Linoserpaturev is a first-in-class, replication-competent, next-generation oncolytic herpes simplex virus-1 (HSV-1) immunotherapy candidate designed for dual activity for oncolysis and immune activation in a single therapeutic. In October 2023, the Company announced that *Nature* published results from the ongoing clinical trial where linoserpaturev was reported to be generally well-tolerated with no dose-limiting toxicity. In the clinical trial, the investigators observed improved median overall survival compared to historical controls after a single linoserpaturev injection in this therapy-resistant condition[1]. The Company and academic collaborators are currently supported by Break Through Cancer to evaluate the effects of repeated linoserpaturev injections in patients with recurrent glioblastoma in an expansion cohort from the phase 1b clinical trial. In October 2025, an original manuscript, published in *Science Translational Medicine* reported collected findings from a comprehensive analysis of 97 serial tumor biopsies collected from two patients treated with repeated administrations of linoserpaturev in arm C. Lastly, in February 2026, *Cell* published an original manuscript showing that a single linoserpaturev treatment triggered persistent T-cell infiltration and antitumor immunity against glioblastoma, with key immune features associated with longer survival. Linoserpaturev previously received Fast Track Designation and Orphan Drug Designation for the treatment of rHGG from the FDA.

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 and is currently in an ongoing phase 3 clinical trial in NSCLC. Linoserpaturev is the lead product candidate from the HSV platform and is currently in an ongoing phase 1b clinical trial in rHGG. 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 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; the timing of expected BLA

submissions; 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 commercialize any approved 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.

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

1. Ling AL, et al. Nature. 2023;623:157-166.