Candel Therapeutics Showcases Immunotherapy Leadership at SITC 2025, Demonstrating Integration of Clinical Innovation, Multi-Omics, and Artificial Intelligence to Advance Next-Generation Immunotherapies in Solid Tumors

Nov 4, 2025

- *Invited presentation followed by panel discussion on the next wave of innovation in immunotherapy of cancer: Paul Peter Tak, M.D., Ph.D., FMedSci, Candel's President and CEO, will present the phase 3 clinical trial of CAN-2409 in newly diagnosed, localized prostate cancer, which achieved its primary endpoint, supported by secondary endpoints*
- *Poster presentation: Daniel Sterman M.D., Professor at NYU Langone Health will present 'Multi-omics analysis of CAN-2409 in non-small cell lung cancer (NSCLC) identifies immune signatures distinguishing response patterns in non-squamous subtypes, offering new insights into mechanisms of tumor response'*
- *Poster presentation: Anne Diers, Ph.D., Vice President of Research at Candel, will present 'Preclinical validation of enLIGHTEN™ Discovery Platform demonstrates that AI-designed viral immunotherapies achieved 60% tumor growth suppression and robust immune activation in breast cancer model, confirming the platform's potential to accelerate precision immunotherapy design'*

NEEDHAM, Mass., Nov. 04, 2025 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a clinical-stage biopharmaceutical company developing multimodal biological immunotherapies to help patients fight cancer, today announced it will deliver three presentations at the Society for Immunotherapy of Cancer (SITC) 40th Anniversary Annual Meeting, taking place November 5–9, 2025, in National Harbor, Maryland.

Together, these presentations underscore Candel's leadership in the development of novel therapeutics, harnessing multi-omics insights and artificial intelligence (AI) to define therapeutic strategies based on a deeper understanding of the tumor microenvironment and biomarkers of response in multiple solid tumors.

"Candel's presentations at SITC 2025 exemplify our innovative approach to the discovery and development of novel immunotherapies," said Paul Peter Tak, M.D., Ph.D., FMedSci, President and Chief Executive Officer of Candel Therapeutics. "By leveraging next-generation research tools we are working to generate deep biological insights that inform every stage of drug development, from bench to bedside and back. This iterative process allows us to refine how we develop a novel class of immunotherapies that have the potential to improve clinical outcome in patients with difficult-to-treat solid tumors."

Invited Faculty Presentation and Panel Discussion:

Paul Peter Tak, M.D., Ph.D., FMedSci, will present Candel's positive phase 3 clinical trial data of CAN-2409 in patients with newly diagnosed, localized prostate cancer and discuss the next wave of innovation in immunotherapy during an invited faculty presentation and subsequent panel discussion. The Company plans to submit a Biologics License Application (BLA) for CAN-2409 in prostate cancer in the fourth quarter of 2026.

Title: Phase 3, Randomized, Placebo-Controlled Clinical Trial of CAN-2409 + Prodrug in Combination with Standard of Care Radiation Therapy for Newly Diagnosed, Localized Prostate Cancer with Curative Intent

Presenter: Paul Peter Tak, M.D., Ph.D., FMedSci, President and CEO of Candel Therapeutics
Session: The Next Wave: Viruses, Cells and Next-gen PD-1 Bispecifics
Date/Time: Friday, Nov. 7, 2025, 3:55 - 5:35 p.m.
Location: Potomac Ballroom – Gaylord National Resort and Convention

CAN-2409 in NSCLC Clinical Data:

Daniel Sterman M.D., Thomas and Suzanne Murphy Professor of Medicine and Cardiothoracic Surgery, NYU Langone Health and Principal Investigator, will present a poster based on integration of clinical and biomarker data from the phase 2a open-label clinical trial of CAN-2409 in patients with stage III/IV NSCLC who had progressed, despite immune checkpoint inhibitor (ICI) treatment (NCT04495153). Patients received two courses of intratumoral CAN-2409 combined with valacyclovir prodrug along with continued ICI treatment. Leveraging previously reported clinical data,[1,2,3] Multi-Omics Factor Analysis (MOFA) was applied to integrate over 3,000 data points from flow cytometry and proteomics analysis of serial samples to provide a deeper understanding of the relationship between clinical and biological responses to CAN-2409.

Key findings include:

- Patients with non-squamous (NSQ) histology exhibited greater expansion of effector and memory T cell populations following CAN-2409 treatment compared to patients with squamous (SQ) histology; latent immune signatures were associated with lack of response and poor outcome in patients with SQ histology
- Robust systemic immune activation in NSQ patients was observed after the second CAN-2409 course, with increased CD8+ central memory T cells and elevated soluble granzymes associated with long-term survival
- Improved immune activation after CAN-2409 administration was observed in patients with NSQ histology compared to those with SQ histology, and this was associated with prolonged overall survival

“The enhanced immune activation and improved survival observed after CAN-2409 administration in patients with non-squamous disease, support the rationale for a phase 3 clinical of CAN-2409 in this subgroup of patients,” said Dr. Sterman.

enLIGHTEN™ Discovery Platform Preclinical Data:

Anne Diers, Ph.D., Vice President of Research at Candel Therapeutics, will present a poster on the third preclinical candidate based on the enLIGHTEN™ Discovery Platform. An AI approach was used to interrogate The Cancer Genome Atlas (TCGA) RNA sequencing data and identify potential therapeutic payloads to be deployed in the tumor microenvironment to treat specific indications. The resulting therapeutic candidate consists of the Alpha-201 vector expressing IL-12 and IL-15 and has been designed for the treatment of breast cancer.

Key findings include:

- Evidence of infection and payload-dependent PBMC-mediated tumor cell killing in vitro, showing that the engineered virus can trigger immune cells to attack cancer cells
- Significant tumor growth suppression (60.0% ± 12.6 vs. vehicle) in the EMT6 mouse model of breast cancer
- Evidence of a synergistic interaction between IL-12 and IL-15 payloads, with the combination producing nominally greater effects than either cytokine alone
- Increased frequency of circulating Ki67+ CD8+ T cells, natural killer cells, and conventional dendritic cells type 2, as well as upregulation of inflammatory response pathways, including IFN-gamma/alpha responses, upon treatment with Alpha-201 IL-12-15

“The enLIGHTEN™ platform provides a new, systematic approach to cancer immunotherapy development,” said Francesca Barone, M.D., Ph.D., Chief Scientific Officer at Candel. “By rationally identifying optimal combinations of immune targets for specific tumor types and validating them using our viral vector engineering capabilities, we can design multimodal therapies with the potential to overcome the immunosuppressive tumor microenvironment.”

About CAN-2409

CAN-2409 (aglatimagene besadenovec), 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. CAN-2409 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 CAN-2409 in clinical trials with a favorable tolerability profile to date, supporting the potential for combination with standard of care, when indicated.

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 HSV gene constructs, respectively. CAN-2409 is the lead product candidate from the adenovirus platform. The Company recently completed successful phase 2a clinical trials of CAN-2409 in NSCLC and pancreatic ductal adenocarcinoma (PDAC), and a pivotal, placebo-controlled, phase 3 clinical trial of CAN-2409 in localized prostate cancer, conducted under a Special Protocol Assessment agreed with the U.S. Food and Drug Administration (FDA). The FDA also granted Regenerative Medicine Advanced Therapy Designation to CAN-2409 for the treatment of newly diagnosed localized prostate cancer in patients with intermediate-to-high-risk disease, Fast Track Designation in NSCLC and prostate cancer, and both Fast Track Designation and Orphan Drug Designation to CAN-2409 for the treatment of PDAC.

CAN-3110 (linoserpaturev) is the lead product candidate from the HSV platform and is currently in an ongoing phase 1b clinical trial in recurrent high-grade glioma. Initial results were published in *Nature* and *Science Translational Medicine* and CAN-3110 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.

About the enLIGHTEN™ Discovery Platform

The enLIGHTEN™ Discovery Platform is a systematic, iterative HSV-based discovery platform leveraging human biology and advanced analytics to create new multimodal biological immunotherapies for solid tumors. The enLIGHTEN™ Discovery Platform has been designed to deconvolute the characteristics of the tumor microenvironment related to clinical outcomes. These characteristics are rapidly translated into optimized multi-gene payloads of tumor modulators for delivery to the tumor microenvironment for specific indications, disease stages, and rationally designed therapeutic combinations.

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; 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; 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 June 30, 2025, 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] Aggarwal, C., et al., CAN-2409 with continued immune checkpoint inhibitor (ICI) in patients with stage III/IV NSCLC with inadequate response to ICI. World Lung Conference on Lung Cancer, 2025.

[2] Ahn, M.J., et al., Datopotamab Deruxtecan Versus Docetaxel for Previously Treated Advanced or Metastatic Non-Small Cell Lung Cancer: The Randomized, Open-Label Phase III TROPION-Lung01 Study. J Clin Oncol, 2025. 43(3): p. 260–272.

[3] Paz-Ares, L.G., et al., Sacituzumab Govitecan Versus Docetaxel for Previously Treated Advanced or Metastatic Non–Small Cell Lung Cancer: The Randomized, Open-Label Phase III EVOKE-01 Study. Journal of Clinical Oncology, 2024. 42(24): p. 2860–2872.