Candel Therapeutics Announces Positive Interim Data After Repeated Administration of CAN-3110 in Recurrent Glioblastoma and Announces Publication in Science Translational Medicine

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NEEDHAM, Mass., Oct. 14, 2025 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a clinical-stage biopharmaceutical company focused on developing multimodal biological immunotherapies to help patients fight cancer, today announced encouraging interim data from its ongoing phase 1b clinical trial of CAN-3110 (linoserpaturev) in recurrent glioblastoma, and a publication in the high-impact scientific journal Science Translational Medicine.

The research detailed in the publication *"Serial Multiomics Uncovers Anti-Glioblastoma Responses Not Evident by Routine Clinical Analyses,"* published on October 8, 2025 (link to abstract), was led by E. Antonio Chiocca, M.D., Ph.D., Executive Director of the Center for Tumors of the Nervous System at the Mass General Brigham Cancer Institute, as part of the multi-institutional Break *Through* Cancer Accelerating GBM Therapies Through Serial Biopsies TeamLab.

The publication presents findings from the comprehensive analysis of 97 serial tumor biopsies collected from two patients treated with repeated administrations of CAN-3110 in Cohort C of the ongoing phase 1b clinical trial (NCT03152318). By integrating multi-omic datasets with conventional histology and standard-of-care brain magnetic resonance imaging (MRI), the study revealed a discordance between immune biomarkers and histologic evidence of response on the one hand and imaging results on the other. Biopsy analyses demonstrated that CAN-3110 induced dynamic spatial and temporal remodeling of the tumor microenvironment, where tumor cells are replaced by immune cells. In one of the two patients, this process resulted in a complete pathological response. Interestingly, immune infiltration leads to an apparent increase in tumor size on MRI, which may be mistakenly interpreted as disease progression. These results underscore the limitations of conventional imaging in evaluating the response to viral immunotherapy and highlight the importance of overall survival (OS) data, supported by histology.

Among the key discoveries, the investigators reported the expansion of novel tissue-resident effector memory T cell clonotypes specifically targeting CAN-3110 epitopes, together with the expression of HLA-presented immunopeptides, including cancer-associated antigens. These findings provide evidence for both viral- and tumor-specific immune activation after intra-tumoral injection of CAN-3110.

"These data unveil a critical limitation in glioblastoma clinical trials, demonstrating our inability to accurately assess efficacy of immunotherapies using conventional imaging," said Dr. Chiocca, the principal investigator of the clinical trial. "Through sophisticated analysis of serial biopsy samples, we showed that CAN-3110 can transform the tumor microenvironment. For the first time, we identified T cell clonotypes, specifically reactive against oncolytic HSV viral epitopes, alongside evidence for an antitumoral response, providing support for the dual mechanism of action of CAN-3110."

The Company today also reported updated survival data for all patients enrolled in the phase 1b clinical trial of CAN-3110 in rHGG. Updated median OS (mOS) was 11.8 months (CI: 8.3–14.9) for arm A (n = 41) and 12.0 months (CI: 10.0–NA) for arm B (n = 9), respectively, after a single injection of CAN-3110, consistent with previously reported data for arms A and B. At the time of data cutoff (8/15/2025), one patient from arm A and one patient from arm B were still alive after prolonged follow-up (59.2 and 42.4 months, respectively, after CAN-3110 administration).

At the time of data cutoff, 9 patients in arm C had received multiple administrations of CAN-3110. At the 1×10^8 PFU dose, 3 patients received 4 injections, 1 patient received 5 injections, and 2 patients received 6 injections. At the 1×10^7 PFU dose, 1 patient received 4 injections, and 2 patients received 5 injections. Median follow-up was 8.9 months. Four out of 9 patients were alive at time of data cutoff (range 3.1-28.2 months after initiation of CAN-3110 treatment). Five patients had died, of which 3 died more than one year after initiation of CAN-3110 treatment (range 5.5-21.8 months). With a short follow up time for the most recently dosed patients and 2 additional patients still to be enrolled in arm C, we expect to present mature mOS data and an update on long-term survivors in Q4 2026. Of importance for the study design of a potential pivotal trial, there was no clear-cut evidence that > 4 injections resulted in better clinical outcomes than 4 injections, suggesting that a larger number of CAN-3110 administrations may not be required to achieve optimal efficacy.

"Glioblastoma is among the most difficult cancers to treat, with an expected median overall survival of less than 6 to 9 months in recurrent glioblastoma. The promising data presented today highlight the transformational potential of CAN-3110 in this indication, with OS in individual patients substantially exceeding historical benchmarks," said Francesca Barone, M.D., Ph.D., Chief Scientific Officer of Candel. "These results support the notion that CAN-3110 could uniquely reprogram the cold, immunosuppressive tumor microenvironment, associated with extended survival."

“The encouraging results with CAN-3110 in recurrent glioblastoma strengthen our confidence in the potential of our viral immunotherapy platform to address one of the most devastating cancers,” said Paul Peter Tak, M.D., Ph.D., FMedSci, President and Chief Executive Officer of Candel. “The observed clinical benefit, together with evidence of immune activation in the tumor microenvironment, supports our plans to design a small phase 2 clinical trial of CAN-3110 in recurrent glioblastoma, working closely with investigators, the glioblastoma community, and regulators; CAN-3110 has previously received FDA Fast Track Designation and Orphan Drug Designation for the treatment of recurrent high-grade glioma.”

About CAN-3110

CAN-3110 (linoserpaturev) is a first-in-class, replication-competent herpes simplex virus-1 (HSV-1) next-generation oncolytic viral immunotherapy candidate designed for dual activity for oncolysis and immune activation in a single therapeutic. CAN-3110 is being evaluated in a phase 1b clinical trial in patients with rHGG. In October 2023, the Company announced that *Nature* published results from this ongoing clinical trial. CAN-3110 was generally well tolerated with no dose-limiting toxicity reported. In the clinical trial, the investigators observed improved mOS compared to historical controls after a single CAN-3110 injection in this therapy-resistant condition.[1] The Company and academic collaborators are currently evaluating the effects of repeat CAN-3110 injections in rHGG, supported by the Break Through Cancer foundation.

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. CAN-2409 (aglatimagene besadenovec) is the lead product candidate from the adenovirus platform. The Company recently completed successful phase 2a clinical trials of CAN-2409 in non-small cell lung cancer (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 FDA. The FDA also granted Fast Track Designation and 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 rHGG. Initial results were published in *Nature* and *Science Translational Medicine* and CAN-3110 received Fast Track Designation and Orphan Drug Designation from the FDA for the treatment of 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, including the timing and availability of additional data and key data readout milestones and presentations; 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; 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 Ling AL, et al. Nature. 2023;623(7985):157-166