Candel Therapeutics Reports Extended Survival Tail Observed in Trial of Aglatimagene Besadenovec (CAN-2409) in Advanced Non-Small Cell Lung Cancer Patients with Inadequate Response to Immune Checkpoint Inhibitors

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- *Extended long-term survival observed after an additional year of follow-up in ongoing phase 2a clinical trial, with 50% of 46 patients with advanced non-small cell lung cancer (NSCLC) treated with aglatimagene besadenovec (aglatimagene or CAN-2409) surviving beyond 24 months, despite prior inadequate response to immune checkpoint inhibitors (ICI) and multiple adverse baseline prognostic factors.*
- *Among the patients surviving beyond 24 months and with PD-L1 status available, (17/20) 85% had baseline PD-L1 tumor proportion scores (TPS) below 50% (a population typically less responsive to ICI), supporting the potential of aglatimagene to upregulate PD-L1 in the tumor microenvironment and convert non-responders to ICI into responders.*
- *Median overall survival (mOS) was 25.4 months in the evaluable patients with inadequate response to ICI in cohorts 1 and 2 (per-protocol population), 21.5 months among evaluable patients exhibiting progressive disease at baseline despite prior ICI therapy (cohort 2), and 25.4 months in patients with non-squamous histology within cohort 2, supporting the rationale for a precision medicine-based design for the phase 3 pivotal study planned for initiation in Q2 2026.*
- *Post-treatment tumor biopsies demonstrated an increase in pro-inflammatory gene expression, which was significantly associated with long-term survival, supporting activation of inflammatory pathways within the tumor microenvironment following aglatimagene treatment.*
- *Expansion of T-cell receptor (TCR) repertoire diversity was observed after treatment both within the tumor and in peripheral blood, consistent with broad activation of anti-tumor immunity through enhanced exposure of tumor antigens following aglatimagene therapy.*

NEEDHAM, Mass., March 17, 2026 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a clinical-stage biopharmaceutical company focused on developing multimodal immunotherapies to help patients with cancer, today announced an additional 12 months of extended follow-up from its study of aglatimagene plus valacyclovir in combination with continued ICI therapy in patients with advanced NSCLC who had an inadequate response to prior ICI treatment. Among the 46 patients who received two administrations of aglatimagene (per-protocol population), 23 patients (50%) remained alive at 24 months. Additionally, 16 patients (35%) survived beyond 30 months, 12 patients (26%) survived beyond 36 months, 11 patients (24%) survived beyond 40 months, and 6 patients (13%) exceeded 50 months of survival. These outcomes represent an improvement from the prior data cut, in which 39% of the patients in the per-protocol population were alive at 24 months, with 10 patients surviving beyond 30 months, 6 patients each beyond 36 and 40 months, and 2 patients beyond 50 months. The extended follow-up further highlights the durability of anti-tumor immunity observed with aglatimagene-based therapy, and the persistence of a long-term survival tail in this difficult-to-treat population.

Histologic analysis of available baseline and tumor biopsies demonstrated that among evaluable patients surviving beyond 24 months and with PD-L1 status available, (17/20) 85% had baseline PD-L1 TPS below 50% (a population typically less responsive to ICI). These findings highlight the ability of aglatimagene to convert immunologically “cold,” ICI-resistant tumors into immune-active microenvironments.

mOS was 25.4 months among 46 evaluable patients who received two courses of aglatimagene (per-protocol population; cohorts 1 and 2). Among evaluable patients with progressive disease at baseline despite prior ICI therapy (cohort 2, n=41), mOS was 21.5 months, and 25.4 months in patients within cohort 2 with non-squamous histology (n=33). These outcomes compare favorably with historical reference mOS of 9.8–11.8 months reported for patients with progressive disease following ICI treatment receiving standard-of-care docetaxel[1,2], representing approximately a two-fold improvement in mOS in this difficult-to-treat population. Aglatimagene maintained its generally favorable tolerability profile throughout the extended follow-up period.

Molecular profiling of paired baseline and post-treatment tumor biopsies revealed that long-term survivors exhibited robust upregulation of genes associated with sustained immune activation and antigen presentation. In particular, enhanced interferon signaling and activation of myeloid and antigen-presenting cell programs were observed, including significant increases in the expression of IFNγ, CSF1, CX3CL1, and IL1β ($p = 0.010$, 0.026, 0.013, and 0.034, respectively). These findings reflect increased local inflammation and recruitment of immune effector populations within the tumor microenvironment following aglatimagene treatment and may have contributed to the durable anti-tumor immune responses observed in long-term survivors.

“These updated survival data further strengthen our previously reported findings, demonstrating the potential of aglatimagene to meaningfully extend survival for patients with advanced NSCLC who have limited treatment options after failing to respond to, or progressing despite, ICI therapy,” said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel Therapeutics. “With its differentiated mechanism of action and favorable safety profile observed to date, aglatimagene represents a novel therapeutic approach for solid tumors, with the potential to improve

outcomes beyond current standards of care. These compelling results reinforce our commitment to advancing this program as we continue to develop new treatment options for patients facing this aggressive disease."

"The biomarker data presented here reinforces the multimodal anti-tumor activity of aglatimagene," said Francesca Barone, PhD, Chief Scientific Officer of Candel Therapeutics. "Consistent with its proposed prime-boost mechanism, we observed expansion of T-cell receptor diversity in both tumor tissue and peripheral blood following treatment, reflecting a broadening of the adaptive immune response. Notably, similar TCR repertoire expansion was previously reported in patients with glioblastoma treated with aglatimagene (see link: Neuro Oncol 2025;27:2617-2631), supporting a consistent immunologic signature across tumor types. Together with the observed activation of interferon signaling and antigen-presentation pathways, these findings highlight aglatimagene's ability to drive both local and systemic anti-tumor immunity."

Based on these findings, together with a strong supporting mechanistic data package, the Company plans to advance this program into a pivotal phase 3 clinical trial in patients with NSCLC with non-squamous histology, with trial initiation expected in the second quarter of 2026. The U.S. Food and Drug Administration (FDA) has previously granted Fast Track designation for aglatimagene plus valacyclovir in combination with ICI therapy for the treatment of patients with stage III/IV NSCLC who are resistant to first-line PD-(L)1 inhibitor therapy and who do not harbor activating molecular driver mutations, or who have progressed on directed molecular therapy.

About aglatimagene besadenovec (CAN-2409)

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 preclinical 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 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 herpes simplex virus (HSV) gene constructs, respectively. Aglatimagene is the lead product candidate from the adenovirus platform. The Company recently completed successful phase 2a clinical trials of aglatimagene in 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. 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.

Linoserpaturev (CAN-3110) 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 linoserpaturev injections. Initial results were published in *Nature* and *Science Translational Medicine* and linoserpaturev 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.

Funding for TCR sequencing and Nanostring work was provided by the Partnership for Accelerating Cancer Therapies (PACT), facilitated by the Foundations for the NIH (FNIH), and the National Cancer Institute-supported CIMAC-CIDC Network. T-cell receptor sequencing was performed by Adaptive Biotechnologies.

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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 programs, including the ability of aglatimagene to treat a broad range of solid tumors and improve disease-free survival, overall survival, and post-progression survival 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 pre-clinical 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 filed and Quarterly Report on Form 10-Q for the quarter ended September 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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