Candel Therapeutics Announces Initiation of Global Pivotal Phase 3 AURORA Trial Evaluating Aglatimagene Besadenovec (CAN-2409) in Advanced Non-Small Cell Lung Cancer Patients with Inadequate Response to Immune Checkpoint Inhibitors

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- *Phase 3 clinical trial will evaluate aglatimagene besadenovec plus valacyclovir in combination with continued pembrolizumab versus standard-of-care docetaxel chemotherapy in patients with metastatic, non-squamous, non-small cell lung cancer (NSCLC) with progressive disease despite prior pembrolizumab and platinum chemotherapy*
- *Global pivotal phase 3 trial expected to enroll patients in 1:1 randomization across more than 150 sites; first site now open for enrollment*
- *Primary endpoint is overall survival*
- *Candel has engaged Parexel International to support execution of this global pivotal trial*

NEEDHAM, Mass., June 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 initiation of the global pivotal phase 3 AURORA trial (NCT07660094), evaluating aglatimagene besadenovec (aglatimagene or CAN-2409) plus valacyclovir in combination with continued pembrolizumab in patients with metastatic non-squamous NSCLC whose disease has progressed despite treatment with pembrolizumab and platinum-based chemotherapy.

The global, randomized, open-label AURORA trial is expected to enroll patients with metastatic Stage IV non-squamous NSCLC across approximately 150 sites worldwide, randomized 1:1 to receive either aglatimagene plus valacyclovir for two injection courses with continued pembrolizumab, or standard-of-care docetaxel chemotherapy. The first trial site is activated and open to enrollment. The study's primary endpoint is overall survival, with secondary endpoints including safety and quality-of-life assessments (NSCLC-SAQ and EORTC QLQ-30). The U.S. Food and Drug Administration (FDA) previously granted Fast Track Designation to aglatimagene for the treatment of NSCLC.

To support the efficient global execution of this pivotal trial, Candel has engaged Parexel International, a leading global clinical research organization with extensive experience in oncology and a global network of nearly 2,500 sites. Parexel will provide clinical operations support across the trial's global sites.

"Patients whose lung cancer progresses despite immune checkpoint inhibitor therapy have limited treatment options, and outcomes with standard chemotherapy remain poor," said Roy Herbst, M.D., Deputy Director and Chief of Medical Oncology and Hematology at Yale Cancer Center and co-Principal Investigator of AURORA. "The survival results observed with aglatimagene in the phase 2 trial are particularly encouraging and support advancing the program into the pivotal phase 3 AURORA trial."

"The initiation of this first global phase 3 trial of a viral immunotherapy at NYU Langone Health marks an important milestone in advancing aglatimagene as a potentially first-in-class immunotherapy for patients with NSCLC," said Daniel Sterman, M.D., Thomas and Suzanne Murphy Professor of Medicine and Cardiothoracic Surgery at NYU Langone Health and co-Principal Investigator. Charu Aggarwal, M.D., M.P.H., Leslye M. Heisler Professor of Medicine at the University of Pennsylvania's Perelman School of Medicine; Section Chief, Thoracic and Head & Neck Cancer; and Director of the Penn Center for Cancer Care Innovation at the University of Pennsylvania is also a co-Principal Investigator on AURORA.

The phase 3 AURORA trial builds on encouraging results from the Company's phase 2 clinical trial (NCT04495153), which demonstrated extended long-term survival in patients with advanced NSCLC who had shown an inadequate response to immune checkpoint inhibitors (ICI). In that trial, 50% of 46 per-protocol patients survived beyond 24 months despite prior inadequate response to ICI and multiple adverse baseline prognostic factors. Among evaluable patients with non-squamous histology and progressive disease at baseline despite prior ICI (intended patient population of the phase 3 trial), median overall survival was 25.4 months.

"This is a pivotal moment for Candel and, most importantly, for the patients we aim to serve," said Paul Peter Tak, M.D., Ph.D., FMedSci, President and Chief Executive Officer of Candel. "Disease progression following ICI therapy remains associated with poor survival outcomes and a substantial unmet medical need. Building on our completed phase 2 clinical trial, we have refined the target patient population by integrating clinical and biomarker insights to maximize the likelihood of success of the phase 3 trial. Our data suggest that aglatimagene may offer a novel approach by inducing an individualized, systemic anti-tumor immune response in patients who have very limited therapeutic options."

Lung cancer is the leading cause of cancer death in the United States, and NSCLC represents approximately 77% of all lung cancer cases.[1] Despite widespread use of ICI as first-line treatment for patients without actionable mutations, approximately 60% of patients experience disease progression within one year.[2] These patients face limited therapeutic options, with docetaxel remaining the current standard of care and delivering a median overall survival of just 9.8 to 11.8 months.[3,4]

About aglatimagene besadenovec (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. 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 use with standard of care, when indicated. Aglatimagene is currently not approved by the 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 is the lead product candidate from the adenovirus platform. The Company 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 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 Designati on 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.

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 the enrollment of the phase 3 AURORA trial evaluating aglatimagene in NSCLC; 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; 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, 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

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