



## **Candel Therapeutics Announces Publication of Phase 2a Trial Data that Demonstrated Prolonged Survival after Systemic Immune Reactivation by Aglatimagene Besadenovec plus Valacyclovir in Patients with Unresectable Stage III/IV NSCLC with an Inadequate Response to ICI**

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- *Peer-reviewed publication in Journal for ImmunoTherapy of Cancer reports median overall survival of 24.5 months in advanced non-small cell lung cancer (NSCLC) patients with inadequate response to immune checkpoint inhibitors (ICI)*

NEEDHAM, Mass., Oct. 01, 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 publication of final phase 2a clinical trial results ([NCT04495153](#)) of aglatimagene besadenovec (aglatimagene) plus valacyclovir in patients with stage III/IV NSCLC who had shown inadequate response to ICI. The trial demonstrated a median overall survival (mOS) of 24.5 months in the evaluable population, substantially exceeding historical benchmarks for standard-of-care docetaxel chemotherapy in this patient population.

The data is published in the [Journal for ImmunoTherapy of Cancer](#), a leading peer-reviewed oncology journal, providing independent validation of the clinical significance of aglatimagene in patients with advanced NSCLC with an inadequate response to ICI.

Patients with unresectable stage III/IV NSCLC who progress on ICI face limited treatment options and poor survival outcomes. Current standard of care with docetaxel chemotherapy yields a median overall survival of only 9.8 to 11.8 months in this population.<sup>1,2</sup> The phase 2a trial enrolled 46 evaluable patients receiving two courses of aglatimagene plus valacyclovir in combination with continued ICI therapy (per protocol population). Among patients with progressive disease at baseline despite ICI treatment (cohort 2, n=41), mOS was 21.5 months. Notably, 37% of patients with progressive disease on ICI remained alive beyond 24 months at the time of data cutoff, demonstrating a prolonged survival tail not typically observed in this setting.

Non-squamous NSCLC has also emerged as a key predictor of enhanced clinical benefit. In the evaluable population of patients with non-squamous histology and progressive disease on ICI (n=33), mOS reached 25.4 months, with 14 of 15 patients surviving beyond 24 months and 9 of 9 patients surviving beyond 30 months having non-squamous disease. Exploratory analysis in the intention-to-treat cohort of non-squamous patients showed mOS of 16.7 months, still longer than the 12.3-month benchmark reported with docetaxel in this setting in published trials.

Mechanistic studies revealed systemic immune activation following treatment. Among evaluable patients with >1 lesion (n=35), 69% exhibited systemic clinical response with reduction of uninjected lesions, indicating an abscopal response. Biomarker analysis demonstrated increased cytotoxic T cell infiltration in tumor tissue, expansion of activated CD8+ effector and central memory T cells in peripheral blood, and elevated serum levels of granzymes after the second aglatimagene injection, with changes most pronounced following the second administration. Multi-omics factor analysis identified coordinated immune activation patterns associated with improved survival. Patients who survived beyond 24 months exhibited significantly higher levels of key immune markers, including granzyme B and granzyme H, compared to those who died earlier.

Treatment with aglatimagene plus valacyclovir was generally well tolerated, with the most common adverse events being mild flu-like symptoms (fatigue, nausea, pyrexia) that were predominantly grade 1 and 2. Grade 3 treatment-related adverse events were reported in 13.7% of patients. No dose-limiting toxicities or unexpected safety signals were identified during extended follow-up.

"These peer-reviewed results confirm that aglatimagene has the potential to extend survival for patients with advanced non-small cell lung cancer who have limited options after immune checkpoint inhibitors fail to control their cancer," said Charu Aggarwal, MD, MPH, Leslye Heisler Professor of Medicine at the University of Pennsylvania's Perelman School of Medicine and lead investigator of the trial. "The magnitude of benefit observed, particularly in patients with non-squamous disease, is striking, and represents an important potential advance for this patient population."

Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel commented, "Aglatimagene's ability to reinvigorate anti-tumor immunity in checkpoint-refractory patients through a systemic immune response, combined with its favorable safety profile, positions this approach as a potentially transformative option for patients with limited therapeutic alternatives. These results support the advancement of our pivotal phase 3 AURORA trial, which is enrolling patients globally."

The global phase 3 AURORA trial is enrolling patients across approximately 150 sites worldwide. The trial is evaluating aglatimagene plus valacyclovir in combination with continued pembrolizumab versus standard-of-care docetaxel in patients with metastatic stage IV non-squamous NSCLC who have experienced disease progression despite prior pembrolizumab and platinum-based chemotherapy.

### **About 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. 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 nonclinical 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 U.S. Food and Drug Administration (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 besadenovec (aglatimagene) is the lead product candidate from the adenovirus platform. The Company completed successful phase 2a clinical trials of aglatimagene in non-small cell lung cancer (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 Designation in NSCLC, and both Fast Track Designation and Orphan Drug Designation to aglatimagene for the treatment of PDAC.

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, 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](http://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 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 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.

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<sup>1</sup> Paz-Ares LG et al. J Clin Oncol 2024;42:2860-2872

<sup>2</sup> Ahn MJ et al. J Clin Oncol 2024;43:260-272