Candel Therapeutics Receives EMA Orphan Designation for CAN-2409 for the Treatment of Pancreatic Cancer

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NEEDHAM, Mass., July 24, 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 that the European Medicines Agency (EMA) has granted Orphan Designation for CAN-2409 (aglatimagene besadenovec) for the treatment of pancreatic cancer. This designation complements CAN-2409's existing U.S. Food and Drug Administration (FDA) Orphan Drug Designation and FDA Fast Track Designation for the treatment of pancreatic ductal adenocarcinoma (PDAC) awarded to CAN-2409 in April 2024 and December 2023, respectively, and underscores the significant unmet medical need in this disease beyond the U.S.

CAN-2409 is an investigational, off-the-shelf, replication-defective adenovirus engineered to deliver the herpes simplex virus thymidine kinase (HSV-tk) gene to tumor cells. When administered with a prodrug (valacyclovir or acyclovir), the HSV-tk enzyme converts the prodrug into DNA-incorporating nucleotide analogs, causing immunogenic cell death and the release of tumor (neo)antigens within the tumor microenvironment (TME). This mechanism has the potential to induce an individualized, systemic immune response against multiple therapy-resistant solid tumors, including prostate cancer, non-small cell lung cancer (NSCLC), and PDAC.

The Company previously reported positive overall survival (OS) data from its randomized controlled phase 2a clinical trial of CAN-2409 plus valacyclovir in borderline resectable PDAC, demonstrating remarkable survival benefits with estimated median OS of 31.4 months in the CAN-2409 plus standard of care arm versus 12.5 months in the standard of care control arm, supported by immunological biomarker data. Notably, three of seven patients treated with CAN-2409 were still alive at the time of data cut-off (February 20, 2025) with survival of 66.0, 63.6 and 35.8 months after enrollment, respectively, suggesting a long tail of survival.

"Pancreatic cancer remains one of the most challenging malignancies to treat, particularly in patients whose disease is unresectable," said Garrett Nichols, MD, MS, Chief Medical Officer at Candel. "We observed that CAN-2409 profoundly remodels the tumor microenvironment, transforming it from 'cold' (non-inflamed and immunosuppressive) to 'hot' (inflamed with active immune infiltration) and extends survival."

The EMA grants Orphan Designation to drugs and biologics intended for the treatment, diagnosis or prevention of rare, life-threatening or chronically debilitating diseases or conditions that affect fewer than five in 10,000 people in the European Union. Orphan Designation allows pharmaceutical companies certain benefits, including reduced regulatory fees, clinical protocol assistance, research grants and up to 10 years of market exclusivity in the European Union, if approved.

"Receiving EMA Orphan Designation for CAN-2409 represents a significant regulatory milestone for CAN-2409 in this disease," said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. "This designation, alongside our existing FDA Orphan Drug and Fast Track Designations for CAN-2409 in PDAC, underscores the promise of our novel multimodal immunotherapy approach. The notable benefits we've observed with CAN-2409, including evidence of a long tail of survival, highlight the transformative potential of this immunotherapy. As we advance our regulatory strategy across global markets, we remain committed to bringing CAN-2409 to patients who face limited therapeutic options. We look forward to continuing our development efforts and working with regulatory authorities across the world to make this innovative therapy available to patients in need."

CAN-2409 has received regulatory designations recognizing its potential across multiple solid tumor indications. In addition to the EMA Orphan Designation announced today and the FDA Orphan Drug Designation and FDA Fast Track Designation for PDAC mentioned above, CAN-2409 has also received FDA Fast Track Designation for NSCLC and localized prostate cancer, as well as FDA Regenerative Medicine Advanced Therapy designation (RMAT) for intermediate-to-high risk, localized prostate cancer.

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 protein promotes 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 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. 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 PDAC, and a pivotal, placebo-controlled phase 3 clinical trial of CAN-2409 in localized prostate cancer, conducted under a Special Protocol Assessment (SPA) agreed with the FDA. Additionally, the FDA very recently granted Regenerative Medicine Advanced Therapy (RMAT) Designation to CAN-2409 for the treatment of newly diagnosed localized prostate cancer in patients with intermediate-to-high-risk disease.

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 (rHGG). Initial results were published in *Nature* 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.

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 Orphan Designation. 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 March 31, 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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