Candel Therapeutics Receives Orphan Drug Designation from the European Medicines Agency for CAN-2409 in Glioma

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NEEDHAM, Mass., Sept. 15, 2022 (GLOBE NEWSWIRE) -- Candel Therapeutics, Inc. (Nasdaq: CADL) (Candel or the Company), a late clinical stage biopharmaceutical company developing novel oncolytic viral immunotherapies, today announced that the European Medicines Agency (EMA) Committee for Orphan Medical Products (COMP) has issued a positive opinion on the Company's application for orphan drug designation for CAN-2409 for the treatment of glioma. CAN-2409, a genetically modified adenovirus and the Company's most advanced investigational therapy, is currently being evaluated in multiple phase 2 and phase 3 clinical trials for lung, brain, pancreatic and prostate cancers.

The orphan drug designation follows the U.S. Food and Drug Administration (FDA) fast track designation, which was granted in June 2021, for CAN-2409 in combination with valacyclovir following standard of care treatment in newly diagnosed high-grade glioma.

Paul Peter Tak, MD, PhD, FMedSci, President and CEO of Candel, said, "Glioma, while mercifully rare, is a devastating disease with significant morbidity and mortality. The EMA's orphan drug designation recognizes the high unmet need and the potential of CAN-2409 in this patient population. We look forward to working with the EMA and FDA in an effort to bring our investigational medicine to patients as we initiate our phase 3 clinical trial of CAN-2409 in high-grade glioma this year."

Orphan drug designation in the European Union (EU) is granted by the European Commission based on a positive opinion issued by the EMA COMP. The EMA's orphan drug designation is potentially available to companies developing treatments for life-threatening or chronically debilitating conditions that affect no more than five in 10,000 persons in the EU. In addition, there must be sufficient clinical or non-clinical data to suggest the product candidate may produce clinically relevant outcomes, and grounds to indicate it can provide a significant benefit over any currently authorized products. The designation can provide financial and regulatory incentives, including a 10-year period of marketing exclusivity in the EU after product approval, protocol assistance from the EMA at reduced fees during the product development phase and access to centralized marketing authorization.

About CAN-2409

CAN-2409, Candel's most advanced oncolytic viral immunotherapy product candidate, is a genetically modified adenovirus that is designed to encode the herpes simplex virus thymidine kinase (HSV-tk) gene. HSV-tk is an enzyme that locally converts orally administered valacyclovir into a toxic metabolite that kills infected and nearby cancer cells. Intratumoral administration of CAN-2409 results in immunogenic cell death, followed by the release of tumor-specific neoantigens in the tumor microenvironment. At the same time, the adenoviral vector elicits a strong pro-inflammatory effect in the tumor microenvironment, creating the optimal conditions to induce a specific CD8+ cytotoxic T cell-mediated immune response against the injected tumor and the uninjected distant metastases. This dual mechanism of antigen unmasking and immune activation may enable CAN-2409 to generate a powerful and lasting immune response against a variety of the patient's tumor-associated neoantigens, minimizing the possibility for immune escape and development of tolerance.

Because of its versatility, CAN-2409 may have the potential to treat a broad range of solid tumors. Encouraging activity has been shown in several preclinical and clinical settings as monotherapy as well as in combination with standard of care radiation therapy, surgery, chemotherapy, and immune checkpoint inhibitor treatment. Furthermore, more than 700 patients have been dosed to date with a favorable safety profile, supporting the potential for combination with other therapeutic strategies without inordinate concern of overlapping adverse events. Currently, Candel is evaluating the effects of treatment with CAN-2409 in high-grade glioma, non-small cell lung cancer, pancreatic cancer, and prostate cancer in ongoing clinical trials.

About Candel Therapeutics

Candel is a late clinical-stage biopharmaceutical company focused on helping patients fight cancer with oncolytic viral immunotherapies. Candel's engineered viruses are designed to induce immunogenic cell death through direct viral-mediated cytotoxicity in cancer cells, thus releasing tumor neo-antigens while creating a pro-inflammatory microenvironment at the site of injection. Candel has established two oncolytic viral immunotherapy platforms based on novel, genetically modified adenovirus and herpes simplex virus (HSV) constructs, respectively. CAN-2409 is the lead product candidate from the adenovirus platform and CAN-3110 is the lead product candidate from the HSV platform. The enLIGHTEN™ Discovery Platform is based on Candel's HSV technology.

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 development programs, include key data readout milestones; expectations regarding the therapeutic benefit of its programs; and expectations regarding cash runway and expenditures. 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; 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 obtain and maintain orphan drug designation for product candidates; the Company’s ability to maintain its intellectual property; the implementation of the Company’s business model, and strategic plans for the Company’s business and product candidates, and other risks identified in the Company’s SEC filings, including the Company’s Quarterly Report on Form 10-Q filed on August 5, 2022, and 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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