Candel Therapeutics to Present Preclinical Data at SITC Annual Meeting Showing Promise for CAN-3110 in Melanoma, Signaling Potential Indication Expansion Beyond Recurrent High-Grade Glioma

November 5, 2024

- *Abstract selected as poster presentation during the Society for Immunotherapy of Cancer (SITC) Annual Meeting shows potent antitumor activity of CAN-3110 in preclinical models of melanoma*
- *CAN-3110's activity is designed to be conditional to the expression of Nestin in cancer cells and is associated with dual activity for oncolysis and immune activation*
- *Findings support potential indication expansion for CAN-3110 beyond high-grade glioma into melanoma, another Nestin-expressing solid tumor*

NEEDHAM, Mass., Nov. 05, 2024 (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 preclinical results and therapeutic potential of CAN-3110 in the Ras-Raf pathway altered melanoma model. The data will be presented at the Society for Immunotherapy of Cancer (SITC) 39th Annual Meeting, taking place November 6-10, in Houston, Texas by Anne R. Diers, PhD, Senior Director of Research at Candel Therapeutics.

CAN-3110 is a first-in-class, replication-competent herpes simplex virus-1 (HSV-1) oncolytic viral immunotherapy candidate designed with dual activity for oncolysis and immune activation. CAN-3110 activity is conditional to the expression of Nestin in cancer cells and specific genetic alterations such as loss of the tumor suppressor gene CDKN2A.

The poster, titled “Therapeutic potential of CAN-3110 in Ras-Raf pathway altered melanoma,” will focus on new data demonstrating the mechanism of action and antitumor activity of CAN-3110 in preclinical models of melanoma, a tumor characterized by high Nestin expression, frequent loss-of-function in CDKN2A, and additional alterations in the Ras-Raf signaling pathway.

“Melanoma exhibits numerous genetic alterations in common with high-grade glioma, a tumor type for which CAN-3110 treatment has consistently shown promising biological and clinical activity,” said Francesca Barone, MD, PhD, Chief Scientific Officer at Candel. “The presence of this genetic profile, and in particular the high expression of Nestin, positions CAN-3110 as a potential first-in-class viral immunotherapy in this new indication. This hypothesis is supported by data showing marked anti-tumor activity in models of melanoma.”

Data presented at SITC showed potent monotherapy, anti-tumor activity of CAN-3110 in both *in vitro* human cell lines and *in vivo* murine models of melanoma. *In vivo*, CAN-3110 exhibited tumor-specific cytotoxicity with dose-dependent inhibition of tumor growth and tumor regression observed in a subset of tumors treated with a high dose of CAN-3110. Cytotoxic activity in melanoma-bearing mice was associated with systemic immune activation and increased proliferation of circulating T cells, mirroring the effect observed in patients with high-grade glioma treated with CAN-3110, as reported last year in *Nature*. CAN-3110 was well-tolerated in mice based on body weight and histopathological analysis following intratumoral administration.

“These encouraging preclinical results validate the broader potential of CAN-3110 in treating a variety of Nestin-positive solid tumors” said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. “The data supports the ability of CAN-3110 to selectively target and kill Nestin-positive tumor cells while eliciting profound immune activation. We are excited by the possibility to develop a new pipeline in a product centered around this first-in-class experimental medicine”.

For more information about the presented data, please visit the Candel website at: https://www.candeltx.com/media/

About CAN-3110

CAN-3110 is a first-in-class, replication-competent herpes simplex virus-1 (HSV-1) oncolytic viral immunotherapy candidate designed with dual activity for oncolysis and immune activation in a single therapeutic. CAN-3110 is being evaluated in a phase 1b clinical trial in patients with recurrent high-grade glioma (rHGG). In October 2023, the Company announced that *Nature* published results from this ongoing clinical trial. CAN-3110 was well tolerated with no dose-limiting toxicity reported. In the clinical trial, the investigators observed improved median overall survival compared to historical controls after a single CAN-3110 injection in this therapy-resistant condition.[1] The Company and academic collaborators are currently evaluating the effects of multiple CAN-3110 injections in rHGG, supported by the Break Through Cancer foundation. CAN-3110 has previously received U.S Food and Drug Administration (FDA) Fast Track Designation and Orphan Drug Designation for the treatment of rHGG.

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 and is currently in ongoing clinical trials in non-small cell lung cancer (phase 2), borderline resectable pancreatic ductal adenocarcinoma (phase 2), and localized, non-metastatic prostate cancer (phase 2b and phase 3). CAN-3110 is the lead product candidate from the HSV platform and is currently in an ongoing investigator-sponsored phase 1b clinical trial in rHGG. 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 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 CAN-3110 to treat high-grade glioma, melanoma or other Nestin-expressing solid tumors; and expectations regarding the potential benefits conferred by orphan drug designation and fast track 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; the Company's ability to continue as a going concern; 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; and other risks identified in the Company's filings with the U.S. Securities and Exchange Commission (SEC) including the Company's most recent Quarterly Report on Form 10-Q filed with the SEC 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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[1] Ling AL, et al. Nature. 2023;623(7985):157-166.