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

April 11, 2024

NEEDHAM, Mass., April 11, 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 that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to CAN-2409, Candel's most advanced multimodal biological immunotherapy candidate, for the treatment of pancreatic cancer.

"We recently reported data from the phase 2 randomized clinical trial of CAN-2409 in borderline resectable pancreatic cancer, showing that CAN-2409, when added to standard of care, more than doubled the median overall survival obtained with standard of care alone," said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. "We are pleased that the FDA has now granted Candel with both Orphan Drug and Fast Track Designation to this program, as we seek to reshape the treatment paradigm in pancreatic cancer."

"Obtaining Orphan Drug Designation marks a significant milestone for Candel, as we continue to develop CAN-2409 for pancreatic cancer," said Garrett Nichols. M.D., M.S., Chief Medical Officer at Candel. "We are excited by this FDA designation, which further supports Candel's efforts in the development of medicines to cure less prevalent yet challenging to treat cancers. The evidence base for CAN-2409 is growing, as we read out clinical trials in patients with difficult-to-treat cancers, such as our recent results in pancreatic ductal adenocarcinoma, and non-small cell lung cancer later in the current quarter."

Earlier this month, Candel reported updated overall survival data from the ongoing randomized phase 2 clinical trial of CAN-2409 plus valacyclovir (prodrug), together with standard of care (SoC) chemoradiation, followed by resection for borderline resectable pancreatic ductal adenocarcinoma (PDAC). The observed data from a March 29, 2024 cut-off showed notable improvement in estimated median overall survival of 28.8 months after experimental treatment with CAN-2409 versus only 12.5 months in the control group. At 24 months, survival rate was 71.4% in CAN-2409 treated patients versus only 16.7% in the control group after chemoradiation. At 36 months, estimated survival was 47.6% in the CAN-2409 group versus 16.7% in the control group. No new safety signals were observed, providing further support that multiple injections of CAN-2409 were generally well tolerated, with no dose-limiting toxicities and no cases of pancreatitis. Analysis of resected tumors showed treatment with CAN-2409 modified the tumor microenvironment, with the local recruitment and activation of cytotoxic lymphocytes and increased levels of proinflammatory cytokines, supporting the activation of a robust systemic anti-tumor immune response.

About Orphan Drug Designation

Orphan Drug Designation is granted by the FDA to drugs or biologics intended to treat a rare disease or condition, defined as one that affects fewer than 200,000 people in the United States. Orphan Drug Designation provides certain financial incentives to support clinical development, and the potential for up to seven years of marketing exclusivity for the product for the designated orphan indication in the United States if the product is ultimately approved for its designated indication.

About CAN-2409

CAN-2409, 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 and induce an individualized, systemic anti-tumor immune response. HSV-tk is an enzyme that locally converts orally administered valacyclovir into a toxic metabolite that kills nearby cancer cells, resulting in the release of a wide variety of cancer antigens. At the same time, the adenoviral serotype 5 capsid protein has the potential to elicit a pro-inflammatory response in the tumor microenvironment. 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 vaccination against a variety of tumor antigens. As a result, CAN-2409 is an off-the-shelf drug candidate, designed to result in an individualized anti-tumor immune response with the potential to treat a broad range of solid tumors. Encouraging monotherapy activity as well as combination therapy activity with SoC radiotherapy, surgery, chemotherapy, and immune checkpoint inhibitors have previously been shown in several preclinical and clinical settings. Furthermore, to date, more than 1,000 patients have been dosed with CAN-2409 with a favorable tolerability profile to date, 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 non-small cell lung cancer (NSCLC), borderline resectable PDAC, and localized, non-metastatic prostate cancer. CAN-2409 has been granted Fast Track Designation by the FDA for treatment of PDAC, stage III/IV NSCLC in patients who are resistant to first line PD-(L)1 inhibitor therapy and who do not have activating molecular driver mutations or have progressed on directed molecular therapy, and treatment of localized, primary prostate cancer in combination with radiotherapy to improve the local control rate, decrease recurrence and improve disease-free survival. Candel's pivotal phase 3 clinical trial in prostate cancer is being conducted under a Special Protocol Assessment by FDA.

About Pancreatic Ductal Adenocarcinoma (PDAC)

Pancreatic cancer is a highly lethal form of cancer, and it is the fourth leading cause of cancer-related death in the United States among both men and women. Based on the National Cancer Institute, Surveillance, Epidemiology and End Results (SEER) database, pancreatic cancer is expected to account for 3.3% of all new cancer cases, with an estimated 64,050 new cases and estimated 50,550 deaths in 2023. Effective therapeutics for pancreatic cancer, including PDAC, which accounts for 90% of all pancreatic carcinomas, are urgently needed.

Surgical resection offers the only chance of cure; thus, a major therapeutic goal for patients with non-metastatic disease is to achieve complete tumor resection. Surgical treatment (pancreaticoduodenectomy, also known as the Whipple procedure) or total or distal pancreatectomy (depending on tumor location) is generally the recommended treatment for patients diagnosed with resectable pancreatic cancer. The addition of adjuvant chemotherapy has been shown to improve survival rates only slightly. To this end, there has been an increase in use of neoadjuvant chemotherapy and chemoradiation regimens for patients with borderline resectable PDAC. Neoadjuvant regimens are intended to debulk the tumor, thereby increasing the proportion of patients who may become eligible for surgical resection and potentially achieve complete resection. Unfortunately, cures often remain elusive as most patients experience disease recurrence due to residual micrometastatic disease.

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 (NSCLC) (phase 2), borderline resectable PDAC (phase 2), and localized, non-metastatic prostate cancer (phase 2 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 recurrent high-grade glioma (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 development programs, including the timing and availability of additional data; expectations regarding the therapeutic benefit of the Company's programs, and the ability of CAN-2409 to improve the median overall survival of patients with PDAC; 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 Annual Report on Form 10-K 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 of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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