Cend Therapeutics Announces Publication of Pancreatic Cancer Trial Data in the Lancet Gastroenterology and Hepatology

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Peer-reviewed study data suggest CEND-1, in combination with gemcitabine and nab-paclitaxel, demonstrates favorable safety and tolerability along with encouraging efficacy

SAN DIEGO, July 06, 2022 (GLOBE NEWSWIRE) -- Cend Therapeutics, Inc. (“Cend”), a privately-held, clinical-stage drug discovery and development company developing a novel approach to enable more effective treatments for solid tumor cancers, today announced that *The Lancet Gastroenterology and Hepatology* published data from the Phase 1b study of CEND-1, Cend’s lead investigational drug, in combination with gemcitabine and nab-paclitaxel for the treatment of first-line, metastatic pancreatic ductal adenocarcinoma (“mPDAC”). The study was published online on July 5, 2022, and can be accessed by visiting https://www.thelancet.com/journals/langas/onlinefirst.

The publication details the results of an open-label, multi-center, Phase 1 trial conducted in 31 patients in the safety population and 29 patients in the efficacy population. The objectives of the study were to determine the safety, tolerability, pharmacokinetics, and preliminary efficacy of CEND-1 in combination with gemcitabine and nab-paclitaxel in patients with mPDAC.

“Pancreatic cancer has always been one of the most difficult tumors to treat. The protective meshwork, or tumor stroma, that surrounds the cancer cells has proved a difficult barrier for chemotherapy drugs to penetrate. In this first-in-human study using the new treatment modality, it appears that CEND-1 may overcome this barrier, and although the sample size was small, we were extremely excited to see such a significant response rate and prolonged progression-free survival with a number of long-term survivors,” said Andrew Dean, M.D., lead investigator at the St. John of God Hospital, Subiaco, Australia. “I believe CEND-1 has the potential to provide a substantial benefit as part of a combination treatment and look forward to the results of the ongoing expansion studies.”

"We are proud to have the very encouraging results of our Phase 1b study of CEND-1 in pancreatic cancer published in a prestigious peer-reviewed journal,” stated Harri Järveläinen, Chief Operating Officer of Cend. “These results reinforce our belief that CEND-1 could become a transformative new medicine for the treatment of pancreatic cancer and other difficult-to-treat solid tumor cancers.”

The data in the publication expand on the preliminary findings presented at the 2020 European Society for Medical Oncology (ESMO) Congress. Importantly, the new results suggest a potential for marked and durable improvement in treatment effectiveness in combination with standard-of-care (“SoC”) drugs for mPDAC. Principal results include:

- CEND-1 was well-tolerated; no dose-limiting toxicities were identified; safety of the combination was consistent with SoC alone
- Pharmacokinetic profile in the target range that is associated with optimal efficacy
- Median Progression-Free Survival 9.7 months
- Median Overall Survival 13.2 months (after extended follow-up of patients continuing treatment)
- Overall Response Rate (Partial Response (PR) + Complete Response (CR)) 59%
- Disease Control Rate at 16 weeks 90%
- CA19-9 circulating tumor biomarker reductions of 50% or greater in 91% of patients

About CEND-1

CEND-1 is an investigational drug that modifies the tumor microenvironment. It is targeted to tumor vasculature by its affinity for *alpha*-v integrins that are selectively expressed in tumor, but not healthy tissue vasculature. CEND-1 is a cyclic peptide that, once bound to these integrins, is cleaved by proteases expressed in tumors to release a peptide fragment, called a CendR fragment, which binds to a second receptor, called neuropilin-1, to activate a novel uptake pathway that allows anticancer drugs to more selectively penetrate solid tumors. The ability of CEND-1 to modify the tumor microenvironment to enhance delivery and efficacy of co-administered drugs has been demonstrated in models of a range of solid tumors.

About Cend Therapeutics

Cend is a privately held, clinical-stage drug discovery and development company focused on a novel approach to enable more effective treatments for solid tumor cancers. The CendR Platform™ provides a tumor-targeted tissue penetration capability to specifically enhance drug delivery to tumors. Cend is also applying its technology to alter immunosuppression selectively within the tumor microenvironment to enable a patient’s immune system and immunotherapies to fight cancer with greater effectiveness. For more information on Cend, please visit www.cendrx.com.

Cend recently announced that it has signed a definitive merger agreement with Caladrius Biosciences, Inc. (www.caladrius.com) to form Lisata Therapeutics. Upon closing, Lisata will be a publicly-traded company with an advanced clinical development pipeline and a cash balance expected to fund development compounds to their next development milestone. The merger is expected to close in the third quarter of 2022.

About Caladrius Biosciences

Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company dedicated to the development of innovative therapies designed to treat or reverse disease. We currently are developing first-in-class autologous cell therapy products based on the finely tuned mechanisms for self-repair that

exist in the human body. Our technology leverages and enables these mechanisms in the form of specific cells, using formulations and modes of delivery unique to each medical indication.

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