Cend Therapeutics' CEND-1 Granted Fast Track Designation for Pancreatic Cancer

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SAN DIEGO, June 29, 2021 (GLOBE NEWSWIRE) -- The US Food and Drug Administration (FDA) has granted Fast Track Development (FTD) status for Cend's investigational drug, CEND-1, for the first-line treatment of metastatic pancreatic ductal adenocarcinoma (mPDAC) in combination with gemcitabine/nab-paclitaxel.

In addition, following encouraging Phase 1b/2 clinical trial results, Cend and collaborators are initiating a controlled Phase 2b clinical trial in mPDAC. CEND-1 was granted Orphan Drug Designation by the FDA for the treatment of pancreatic cancer in January 2019.

"By awarding Fast Track Designation, the FDA has recognized CEND-1's potential to meaningfully improve outcomes for pancreatic cancer patients," said Andrew Dorr, MD, Chief Medical Officer of Cend. "FTD is designed to facilitate the development and expedite the review of investigational treatments that demonstrate the potential to address unmet medical needs in serious or life-threatening conditions."

Cend will also explore applications of CEND-1 in combination with additional agents, including immunotherapies for mPDAC, and plans to expand development into additional solid tumor cancer indications.

About Fast Track Designation

FTD is an FDA process designed to facilitate the development, and expedite the review of, medicines to treat serious conditions and fill unmet medical need. The FDA created this process to help deliver important new drugs to patients earlier, and it covers a broad range of serious illnesses. Fast Track designation can lead to an Accelerated Approval and Priority Review if certain criteria are met.

About Pancreatic Cancer

Pancreatic cancer is the third leading cause of cancer-related death with very poor five-year survival. Globally, pancreatic cancer accounts for over 430,000 deaths each year, including over 48,000 in the US. Pancreatic ductal adenocarcinoma (PDAC) is characterized by marked desmoplasia that creates a dense capsule or stroma surrounding the tumor that contributes to drug resistance due, in part, to poor drug delivery to tumor tissue.

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 vasculature but not normally expressed in vasculature of healthy tissues. 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, to activate a novel uptake pathway that causes anticancer drugs to more selectively penetrate solid tumors.

About Cend Therapeutics

Cend is a clinical-stage biotech company focused on a novel approach to enable more effective treatments for solid tumor cancers. Poor penetration of drugs into tumors is a major issue in cancer therapy as it limits access and therefore efficacy of current therapies. The CendR Platform provides a 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 more effectively fight cancer.

For additional information, please visit www.cendrx.com.