August 13, 2018

CTD Holdings Announces Expanded Access Protocol using Intravenous Trappsol® Cyclo™ for Alzheimer's Disease

Protocol Available on ClinicalTrials.gov

ALACHUA, Fla., Aug. 13, 2018 (GLOBE NEWSWIRE) -- CTD Holdings, Inc. (OTCQB: CTDH), a clinical stage biotechnology company that develops cyclodextrin-based products for the treatment of disease with unmet medical need, announced today that the protocol for use of the company's proprietary hydroxypropyl beta cyclodextrin, Trappsol(R) Cyclo(TM), in a single patient with late onset Alzheimer's Disease is now publicly available on ClinicalTrials.gov (NCT 03624842). The Principal Investigator for the protocol is Diana Kerwin, M.D., President of Kerwin Research Center and a recognized expert in Alzheimer's Disease and memory disorders. The Kerwin Research Center is sponsoring the project with CTD Holdings as collaborating partner.

"With this cooperative research program, we will continue to advance our knowledge of how Trappsol(R) Cyclo(TM) interacts with cholesterol in patients with cholesterol-related disease. This knowledge will help us as we seek to develop therapies for Alzheimer's Disease and other indications," said N. Scott Fine, CTD's Chairman and CEO.

Cholesterol has been linked to the formation of amyloid beta plaques, one of the hallmarks of Alzheimer's disease. Hydroxypropyl beta cyclodextrins have been shown to clear cholesterol from cells, to stabilize cholesterol metabolism, and to reduce the formation of amyloid beta plaques in animal models.

CTD currently supports two clinical trials (NCT02939547 and NCT02912793) using Trappsol(R) Cyclo(TM) intravenously in patients with Niemann-Pick Disease Type C (NPC), a rare and fatal disease in which cholesterol accumulates in every cell in the body. NPC has also been called "Childhood Alzheimer's" due to the cognitive decline which is apparent in many NPC patients.

"I am pleased to be working with CTD on this program, and to build on the platform of safety data and knowledge within the company on cyclodextrins and their potential to address cholesterol-related diseases. With millions suffering from Alzheimer's Disease in the United States alone, this collaboration is very timely," said Dr. Kerwin.

The protocol describes an initial dosing regimen of 500 mg/kg given intravenously, with monthly increases in dose provided that safety and tolerability features are positive.

“We will examine a number of factors to assess the risk-benefit ratio, including brain imaging, adverse events, changes in blood biomarkers, and pharmacokinetic data,” said Sharon Hrynkow, Ph.D., CTD’s Senior Vice President for Medical Affairs. “What we learn will be important not only to the single patient involved in this current project, but also potentially for all of CTD’s clinical studies, including our priority trials on Niemann-Pick Disease Type C.”

About CTD Holdings:
CTD Holdings, Inc. is a clinical-stage biotechnology company that develops cyclodextrin-based products for the treatment of disease. The company’s Trappsol(R) Cyclo(TM), an orphan drug designated product in the United States and Europe, is used to treat Niemann-Pick Disease Type C, a rare and fatal genetic disease, on a compassionate use basis as well as in two ongoing formal clinical trials (Clinical Trials.gov NCT02939547 and NCT02912793). Additional indications for the active ingredient in Trappsol(R) Cyclo(TM) are in development. For additional information, visit the company’s website: www.ctd-holdings.com

Safe Harbor Statement:
This press release contains “forward-looking statements” about the company’s current expectations about future results, performance, prospects and opportunities. Statements that are not historical facts, such as “anticipates,” “believes” and “expects” or similar expressions, are forward-looking statements. These statements are subject to a number of risks, uncertainties and other factors that could cause actual results in future periods to differ materially from what is expressed in, or implied by, these statements. The factors which may influence the company’s future performance include the company’s ability to obtain additional capital to expand operations as planned, success in achieving regulatory approval for clinical protocols, enrollment of adequate numbers of patients in clinical trials, unforeseen difficulties in showing efficacy of the company’s biopharmaceutical products, success in attracting additional customers and profitable contracts, and regulatory risks associated with producing pharmaceutical grade and food products. These and other risk factors are described from time to time in the company’s filings with the Securities and Exchange Commission, including, but not limited to, the company’s reports on Forms 10-K and 10-Q. Unless required by law, the company assumes no obligation to update or revise any forward-looking statements as a result of new information or future events.

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Source: CTD Holdings, Inc.