CTD Holdings Enrolls First Patient in US Phase I Clinical Trial of Trappsol(R) Cyclo(TM) for Treatment of Niemann-Pick Disease Type C

Company Expects Final Data from Trial in 2018

Alachua, FL – (Marketwired) – September 28, 2017 – CTD Holdings, Inc. (OTCQB: CTDH), a clinical stage biotechnology company that develops cyclodextrin-based products for the treatment of disease with unmet medical need, today announced that it has enrolled the first patient in the Company's US Phase I clinical trial evaluating the intravenous administration of Trappsol(R) Cyclo(TM) in patients with Niemann-Pick Disease Type C (NPC). NPC is a rare and fatal genetic disease that impacts the brain, lung, liver, spleen, and other organs. The first patient was enrolled at UCSF Benioff Children's Hospital Oakland, the single site for this trial, by Dr. Caroline Hastings, pediatric hematologist and oncologist. Dr. Hastings is the Principal Investigator for the US Phase I trial.

The Phase I clinical trial will require 12 patients to be fully enrolled. It is a double-blind randomized trial evaluating two doses of Trappsol(R) Cyclo(TM), 1500 mg/kg or 2500 mg/kg, in NPC patients 18 years of age and older. Trappsol(R) Cyclo(TM) will be administered intravenously via bi-monthly injections over a period of 14 weeks. There is no placebo in this trial. In addition to safety outcomes, evaluations will include concentrations of Trappsol(R) Cyclo(TM) in plasma at timed intervals after administration, impact on cholesterol synthesis and metabolism following Trappsol(R) Cyclo(TM) administration, and overall impression of disease progression.

"Enrollment of the first patient at UCSF Benioff Children's Hospital Oakland is a significant milestone for the Company and in the continued development of Trappsol(R) Cyclo(TM) as an approved treatment for NPC, a disease whose treatment is an unmet medical need in the US," said CTD Chairman and CEO, N. Scott Fine. "We expect final data from this clinical trial in 2018. CTD remains grateful for the support and encouragement from patients and their families, as well as researchers, patient advocates, and physicians globally. Together, we are moving efficiently toward gaining market approval for Trappsol(R) Cyclo(TM)."

Trappsol(R) Cyclo(TM) is a parenteral grade of hydroxypropyl beta cyclodextrin, a donut-shaped molecule comprised of seven glucopyranose units. To date, intravenous Trappsol(R) Cyclo(TM) has been administered to 21 NPC patients worldwide, some for more than six years, via Compassionate Use Programs. Data from treating physicians in these Compassionate Use Programs have demonstrated that multiple patients have shown marked improvements in neurological symptoms, lung function or liver morphology, or had stabilization of disease progression, with no significant safety concerns.

"I am excited to be leading this promising clinical trial," said Dr. Hastings, who, in 2009, was also the first physician in the United States to administer Trappsol(R) Cyclo(TM) on a compassionate use basis. "Based on the data generated from Compassionate Use, Trappsol(R) Cyclo(TM) administered intravenously has significant potential to be a safe and effective treatment for NPC, one so sorely needed by NPC patients around the world."

Dr. Hastings' Co-Investigator in the trial is Dr. Benny Liu, Alameda Health System, Oakland, CA, a practicing gastroenterologist and also the first scientist to demonstrate that hydroxypropyl beta cylodextrins were effective in prolonging life and delaying onset of NPC symptoms in an animal model of the disease.

"We are thrilled that the scientist who broke open the cyclodextrin field for NPC patients, Dr. Liu, and the first physician who treated NPC patients compassionately in the US with Trappsol(R) Cyclo(TM) and who has mentored physicians globally to do the same, Dr. Hastings, are leading CTD's US study." said Dr. Sharon Hrynkow, CTD's Senior Vice President for Medical Affairs, "Their early and seminal contributions to this field have already helped many and now we have the opportunity together to help many more."

In addition to the US study, CTD Holdings has initiated a multi-center international Phase I/II clinical trial in Europe, evaluating intravenous administration of Trappsol(R) Cyclo(TM) in NPC patients. Dr. Hastings is the Senior Clinical Advisor for the EU study. CTD previously received Fast Track Designation and Orphan Drug Designation for the use of Trappsol(R) Cyclo(TM) in the treatment of NPC from the U.S. Food and Drug Administration and the European Medicines Agency.

About the Trials
For families interested in learning more about the US trial or the EU trial, please contact CTD's Patient Liaisons:

- Ms. Shannon Reedy, based in the U.S., at Shannon.Reedy@hotmail.com
- Ms. Jackie Imrie, based in the UK, at jackie@jicltd.co.uk
- Dr. Caroline Hastings, Principal Investigator for the US trial and Senior Clinical Advisor to the EU study, at chastings@mail.cho.org, Phone 510-428-3631
- Physicians may contact Dr. Hastings or Dr. Sharon Hrynkow at CTD at Sharon.Hrynkow@cyclodex.com

For additional information, please visit:

Phase I: https://clinicaltrials.gov/ct2/show/NCT02939547

Phase I/II: https://clinicaltrials.gov/ct2/show/NCT02912793

About CTD Holdings:
CTD Holdings, Inc. is a clinical-stage biotechnology company that develops cyclodextrin-based products for the treatment of disease with unmet medical need. 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. 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.

Investor/Media Contact:
Sitrick and Company

Wendy Tanaka
(415) 369-8447
wtanaka@sitrick.com

Thomas Mulligan
(212) 573-6100, Ext. 395
tmulligan@sitrick.com