CTD Holdings Enrolls First Patient in European Phase I/II Clinical Trial of Trappsol® Cyclo™ for Treatment of Niemann-Pick Disease Type C

Company Expects Final Data from Trial by End of 2018

Alachua, FL – (Marketwired) – June 21, 2017 – CTD Holdings, Inc. (OTCQB: CTDH), a clinical stage biotechnology company that develops cyclodextrin-based products for the treatment of disease, today announced that it has enrolled the first patient in the Company's European Phase I/II clinical trial evaluating the intravenous administration of Trappsol® Cyclo™ in patients with Niemann-Pick Disease Type C (NPC), a rare and fatal genetic disease that impacts the brain, lung, liver, spleen, and other organs. The first patient was enrolled at Salford NHS Trust UK by Dr. Reena Sharma, Consultant for Adult Metabolic Medicine and Honorary Senior Lecturer at the Mark Holland Metabolic Unit. Dr. Sharma is also the Coordinating Investigator for the Phase I/II trial in Europe.

The Phase I/II clinical trial, which will include additional sites in the UK and Sweden and is also expected to be expanded to Italy, will require 12 patients to be fully enrolled. The trial will evaluate the safety and efficacy of Trappsol® Cyclo™ in NPC patients ages two and older, with the primary objective of determining the optimum dose for further study. Patients will be randomized into three dose groups of 1500 mg/kg, 2000 mg/kg and 2500 mg/kg of Trappsol® Cyclo™which will be administered via bi-weekly intravenous injections over a period of 48 weeks.

"Enrollment of the first patient at the Salford clinical site is a significant milestone for the Company in the development of this treatment for a devastating disease," said CTD Chairman and CEO, N. Scott Fine. "We expect final data from this important clinical trial by the end of 2018. In addition, we anticipate enrolling the first patient in our U.S. Phase I clinical trial of Trappsol® Cyclo™ in the near future. CTD is grateful for the continued support from the many patient families, researchers and clinicians who have worked with us to get to this point."

Trappsol® Cyclo™ is a parenteral grade of hydroxypropyl beta cyclodextrin, a donut-shaped molecule comprised of seven glucopyranose units. To date, intravenous Trapps Trappsol® Cyclo™ has been administered to 21 NPC patients worldwide, some for more than six years, via Compassionate Use Programs. Data from treating physicians 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 pleased to be participating in this promising clinical trial," said Dr. Sharma. "Based on the data generated from the ongoing Compassionate Use Programs, Trappsol® Cyclo™ administered intravenously has significant potential to be a safe and effective treatment for NPC, a catastrophic condition with a substantial unmet need. I look forward to further evaluating this important drug candidate in a clinical setting."

"NPC is a systemic disease, which is why we are administering Trappsol® Cyclo™ intravenously in this study," said Dr. Sharon Hrynkow, CTD's Senior Vice President for Medical Affairs. “We look forward to working with our colleagues to enroll additional patients in Salford, and other sites, as we move this promising drug candidate forward in this Phase I/II study.”

In addition to the European study, CTD Holdings has initiated a Phase I clinical trial in the U.S. evaluating intravenous administration of Trappsol® Cyclo™ in NPC patients. CTD previously received Fast Track Designation and Orphan Drug Designation for the use of T Trappsol® Cyclo™ in the treatment of NPC from the U.S. Food and Drug Administration and the European Medicines Agency.

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® Cyclo™, 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® Cyclo™, 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.

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

- Ms. Jackie Imrie, based in the UK, at jackie@jicltd.co.uk
- Ms. Shannon Reedy, based in the U.S., at Shannon.Reedy@hotmail.com

- 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

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