# CTD Holdings Establishes Second Clinical Trial Site for US Phase I Clinical Study of Trappsol<sup>®</sup> Cyclo<sup>™</sup> for Treatment of Niemann-Pick Disease Type C

## Patients to be Enrolled at Atlantic Health System's Morristown Medical Center, Morristown, New Jersey

ALACHUA, FL – (Marketwired) – October 05, 2018 – 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 begun recruiting patients at Atlantic Health System's Morristown Medical Center, in Morristown, New Jersey for its Phase I clinical study to evaluate the intravenous administration of Trappsol<sup>®</sup> Cyclo<sup>™</sup> 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 Principal Investigator for this clinical site is Dr. Darius Adams, MD, Medical Director, Atlantic Health System Jacobs Levy Genomic Medicine and Research Program, and a clinical geneticist with extensive expertise in metabolic diseases and in clinical research more broadly.

"I am pleased to bring Morristown Medical Center and Goryeb Children's Hospital into this clinical trial. With no approved treatments for NPC in the United States, this study will help establish the safety and tolerability profile for Trappsol<sup>®</sup> Cyclo™ administered intravenously and help patients in the NPC community who so desperately need treatment options," said Dr. Adams.

"The initiation of the Morristown site is another significant milestone for the Company in the development of this important treatment for a devastating disease," said CTD Chairman and CEO, N. Scott Fine. "With an East Coast site and a West Coast site, we are working to make the trial as accessible as possible to those who wish to join."

The first site to open in this study is at UCSF Benioff Children's Hospital Oakland under the direction of Dr. Caroline Hastings, MD, a pediatric haematologist/oncologist. Dr. Hastings is also the first physician in the US to provide any form of cyclodextrin (CTD's Trappsol(R) brand) to patients with NPC. She did this on a compassionate use basis starting in 2009.

The Phase I trial in the United States complements a Phase I/II trial in Europe and Israel.

The Company has Orphan Drug designation for the use of Trappsol<sup>®</sup> Cyclo<sup>™</sup> in NPC from the U.S. Food and Drug Administration and Fast Track Designation, also from FDA, and has Orphan Drug Designation from the European Medicines Agency.

For families interested in learning more about the Morristown site, please contact Ms. Christina Flora, Study Coordinator, at <a href="mailto:Christina.Flora@atlantichealth.org">Christina.Flora@atlantichealth.org</a> or Ms. Shannon Reedy, CTD Family Liaison at Shannon.Reedy@hotmail.com.

For further information on CTD clinical programs, see ClinicalTrials.gov (NCT02939547 and NCT02912793) or send an email to Dr. Sharon Hrynkow, PhD, Senior Vice President for Medical Affairs, CTD Holdings, at: Sharon.Hrynkow@cyclodex.com.

### **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® 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, on a compassionate use basis as well as in two ongoing formal clinical trials (ClinicalTrials.gov NCT02939547 and NCT02912793). 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.

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