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CTD Announces Home-Based Dosing of First Patient in US Extension Protocol of Clinical Trial using Intravenous Administration of Trappsol (R) Cyclo (TM) for Niemann-Pick Disease Type C

ALACHUA, FL / ACCESSWIRE / May 23, 2019 /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 its first home-based infusion of its proprietary formulation of hydroxypropyl beta cyclodextrin, Trappsol® Cyclo™, in a formal clinical trial. The trial is "An Open-Label Extension Study of the Long-Term Safety and Efficacy of Intravenous Trappsol® Cyclo™ (HPBCD) in Patients with Niemann-Pick Disease Type C (NPC-1)" (ClinicalTrials.gov [NCT03893071](https://clinicaltrials.gov/ct2/show/study/NCT03893071)) in the United States.

"Today's infusion is a milestone for all who have supported CTD's clinical program from the very beginning. We are pleased to be able to provide home-based infusions to NPC patients even as we continue to gather data needed to support market registration of Trappsol® Cyclo™ for NPC." said N. Scott Fine, CTD's Chairman and CEO. "As we work to advance the intravenous route of Trappsol® Cyclo™ administration in NPC patients, we are mindful that so many families and so many patients have sacrificed countless hours in the hospital setting in order to support our formal trial. Today, we are pleased to move the center of gravity out of the hospital and into the home, even as we continue to gather data that is expected to support ultimate registration of our drug for the treatment of NPC."

CTD's partner in providing home-based infusions of its drug product is United Biosource LLC (UBC). UBC identifies local health care professionals in the area of participating patients to administer CTD's Trappsol® Cyclo™ drug intravenously and to relay key information back to the parent clinical site overseeing the trial.

"As we listened to patients and families about their needs, it was clear that home-based infusions would make family life easier for those patients wishing to continue on our drug after completion of the formal trial. We believe that most if not all patients who are eligible for the US Extension Protocol will opt for home-based infusions," said Sharon Hrynkow, PhD, CTD's Chief Scientific Officer and Senior Vice President for Medical Affairs.

Home-based infusions are an option for eligible patients who have completed the US-based Phase I clinical trial using Trappsol® Cyclo™ intravenously in NPC (see Clinical Trials.gov [NCT02939547](https://clinicaltrials.gov/ct2/show/study/NCT02939547)). The Extension Protocol allows for infusions either at the main hospital site or at home, with periodic assessments at the main site. The two hospital sites participating the Phase I trial are UCSF Benioff Children's Hospital Oakland, California, led by Caroline Hastings, MD and Benny Liu, MD, and Morristown Medical Center of the Atlantic Health System, New Jersey, led by Darius Adams, MD.

Enrollment for CTD's Phase I trial nearing completion. For more information, interested patients and their caregivers should contact CTD Family Liaison Shannon Reedy at Shannon.Reedy@hotmail.com, Dr. Hastings at chastings@mail.cho.org for the Oakland, CA site or Dr. Adams at darius.adams@atlantichealth.org for the Morristown, NJ site.

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, on a compassionate use basis as well as in three ongoing formal clinical trials (Clinical Trials.gov [NCT02939547](https://clinicaltrials.gov/ct2/show/study/NCT02939547), [NCT02912793](https://clinicaltrials.gov/ct2/show/study/NCT02912793) and [NCT03893071](https://clinicaltrials.gov/ct2/show/study/NCT03893071)). 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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