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Cyclo Therapeutics Announces Completion of Enrollment in its Phase I Trial to Evaluate Trappsol® Cyclo™ for the Treatment of Niemann-Pick Disease Type C

Top line results are expected to be available in February 2020

GAINESVILLE, Fla.--(BUSINESS WIRE)-- Cyclo Therapeutics, Inc. (OTCQB: CTDH), formerly CTD Holdings, Inc., a biotechnology company that develops cyclodextrin-based products for the treatment of disease, today announced that it has completed patient enrollment in its Phase I trial to evaluate the safety and tolerability of Trappsol® Cyclo™ administered intravenously to Niemann-Pick Disease Type C (NPC) patients.

“Today’s ‘Last-Patient-In’ announcement is a significant milestone for our company and the NPC community,” said Chairman and CEO, N. Scott Fine. “It completes another important step in our development and registration strategies for Trappsol® Cyclo™ to treat NPC, a disease which causes much suffering for the patients and their families. We are delighted to share this news with our many supporters and all of our stakeholders.”

Niemann-Pick Disease Type C is a rare and fatal genetic disease affecting 1 in 100,000 live births globally. NPC affects every cell in the body due to a defect in the NPC protein which is responsible for cholesterol processing in the cell. NPC causes symptoms in the brain, liver, spleen, lung and other organs. There are no approved drug therapies for NPC in the United States and only one approved therapy in Europe.

“We thank all of the patients and their caregivers who have or are currently participating in this trial. We recognize the sacrifice of time and energy on the part of families as they participate in this trial,” said Sharon Hrynkow PhD, Chief Scientific Officer and Senior Vice President for Medical Affairs. “We are also deeply grateful to the study team at UCSF Benioff Children’s Hospital Oakland, especially Co-Principal Investigators Caroline Hastings MD and Benny Liu, MD, for all that they have done and continue to do to support the development of this drug.”

It is anticipated that data from the last patient enrolled in the study will be available in February 2020. Cyclo Therapeutics Inc. will then unblind the study results and analyze the data. Data from the current study combined with those of the companion Phase I/II study, nearing completion of enrollment in EU-Israel (ClinicalTrials.gov NCT02912793), are

expected to be used in the company's market registration applications.

About The Clinical Trial:

Complete enrollment in the study required 12 patients, all of whom were enrolled at one site in the United States, UCSF Benioff Children's Hospital Oakland, CA with Co-Principal Investigators Caroline Hastings, MD and Benny Liu, MD. The study is a randomized, double-blind study using Trappsol® Cyclo™ intravenously in NPC patients age 18 years and older. Study subjects receive 7 doses of the drug at either 1500 mg/kg or 2500 mg/kg and are assessed for adverse events, markers for cholesterol metabolism following drug administration, and symptomatic changes using an NPC severity scoring tool, among other tests. (See ClinicalTrials.gov NCT02939547 for additional details.)

The company has reported initial data from this study that suggests a favorable safety profile; a temporal link between administration of the drug and clearance of cholesterol from cells; presence of the drug in the cerebrospinal fluid following IV administration; and reduction in a neuron-specific biomarker, tau, that is associated with neuronal degeneration in NPC patients.

About Cyclo Therapeutics:

Cyclo Therapeutics, 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 the subject of three ongoing formal clinical trials for Niemann-Pick Disease Type C, a rare and fatal genetic disease, (ClinicalTrials.gov NCT02939547, NCT02912793 and NCT03893071) and an Expanded Access program for late-onset Alzheimer's Disease (NCT03624842). Additional indications for the active ingredient in Trappsol® Cyclo™ are in development. For additional information, visit the company's website: www.cyclotherapeutics.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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