

# Cyclo Therapeutics, Inc. Announces Maurizio Scarpa, MD as EU Coordinating Investigator for the Company's Pivotal Trial in Niemann-Pick Disease Type C

## Reena Sharma, MD will serve as EU Coordinating Investigator for Extension Protocol

ALACHUA, FL – (Businesswire) – October 9, 2019 – Cyclo Therapeutics, Inc. (OTCQB: CTDH), formerly CTD Holdings, Inc., a biotechnology company that develops cyclodextrin-based products for the treatment of disease with unmet medical need, today announced that Professor Maurizio Scarpa, MD, PhD, Director of the Regional Coordinating Center for Rare Disease, Udine University Hospital, Udine, Italy and Professor of Pediatrics, University of Padova, Italy, will serve as EU Coordinating Investigator for the company's upcoming Phase III pivotal trial in Niemann Pick Disease Type C. Dr. Scarpa is also expected to serve as site director of the Udine Hospital program in the pivotal trial. The company is currently designing the global Phase III pivotal trial in NPC.

Niemann-Pick Type C Disease (NPC) is a rare and fatal genetic disease affecting 1 in 100,000 live births globally. NPC affects every cell in the body due to the 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.

Company Chairman and CEO N. Scott Fine said, "Dr. Scarpa brings to this role not only his deep clinical trial expertise and commitment to helping NPC patients, but he also brings a willingness to work across Europe through his many contacts to assist in patient recruitment for the full study. We look forward to working with Dr. Scarpa in this new capacity."

The EU Coordinating Investigator role is required by EU regulatory authorities for studies that will lead to Market Approval Applications involving more than one EU member state.

The company is currently completing enrollment of its Phase I/II trial on NPC in Europe and Israel, with Dr. Reena Sharma as EU Coordinating Investigator (See [ClinicalTrials.gov NCT 02912793](https://clinicaltrials.gov/NCT02912793)). Dr. Sharma is Senior Consultant in Metabolic Disorders at the Salford Royal Foundation Trust Hospital, Salford, UK, and is a site director for the trial at Salford. Approved sites for the Phase I/II trial are located in the UK (three sites), Sweden (1 site), Italy (1 site) and Israel (2 sites). Dr. Sharma will serve as the EU Coordinating Investigator for the Extension Protocol for the current trial.

"We are grateful for the support and leadership of Dr. Sharma in advancing the Phase I/II trial, and now for her additional role as Coordinating Investigator for the Extension Protocol in the EU," said Sharon Hrynkow, PhD, Company Chief Scientific Officer. "We look forward to our continued collaboration with Dr. Sharma on multiple levels as the pivotal trial is fully launched."

***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 in three ongoing formal clinical trials for Niemann-Pick Disease Type C, a rare and fatal genetic disease, (ClinicalTrials.gov [NCT02939547](#), [NCT02912793](#) and [NCT03893071](#)) and in 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](http://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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