

# Cyclo Therapeutics Phase 3 Pivotal Program Can Begin Enrollment per US FDA

Cyclo Therapeutics will now proceed in the US with its Phase 3 clinical trial of Trappsol® Cyclo™ for treatment of Niemann-Pick Disease Type C

GAINESVILLE, FL – (Businesswire) – 21 October 2020 – Cyclo Therapeutics, Inc. (OTCQB: CTDH), a clinical stage biotechnology company developing a cyclodextrin platform for the treatment of Neurodegenerative Diseases, including their lead candidate (Trappsol® Cyclo™) in the treatment of Niemann-Pick Disease Type C (NPC) today announced that the company received notification from the US FDA that enrollment can proceed for its Phase 3 global pivotal clinical trial, “A Phase 3, Double-blind, Randomized, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety, Tolerability, and Efficacy of 2000 mg/kg of Trappsol® Cyclo™ (Hydroxypropyl-β-cyclodextrin) and Standard of Care Compared to Placebo and Standard of Care in Patients with Niemann-Pick Disease Type C1”.

“We are very pleased to receive the FDA’s notification that we can proceed with the Phase 3 clinical trial. This announcement signifies the most significant milestone for our company but also for the patients, families and caregivers in the NPC Community as well.” said company CEO N Scott Fine. “We will continue to collaborate with the NPC community as we drive this study forward towards market authorization as rapidly as possible.”

“Through our Fast Track designation, we were able to engage in ongoing collaboration with the US FDA which has enabled us to proceed quickly in the US,” said company Chief Regulatory Officer Michael Lisjak. “We will continue to execute on our parallel efforts with the EMA and other regulatory bodies to achieve a similar outcome on our Phase 3 pivotal program outside the US.”

“We are grateful to the FDA for the positive feedback on our Phase 3 pivotal study design,” said company Chief Scientific Officer and Senior Vice President for Medical Affairs, Sharon Hrynkow, PhD. “We are excited to launch our first clinical sites in the US in the near term, with confidence that the European sites and other global sites will follow in short order.”

Niemann-Pick Disease Type C is a rare genetic disease affecting 1 in 100,000 live births globally. NPC affects every cell in the body due to a defect in the NPC1 protein which is responsible for cholesterol processing in the cell. NPC causes symptoms in the brain, liver, spleen, lung and other organs and often leads to premature death. There are no approved drug therapies for NPC in the United States and only one approved therapy in Europe.

***About Cyclo Therapeutics:***

Cyclo Therapeutics, Inc. is a clinical-stage biotechnology company that develops cyclodextrin-based products for the treatment of Niemann-Pick Disease Type C and Alzheimer's 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](#)). The company is planning an early phase clinical trial using Trappsol® Cyclo™ intravenously in Alzheimer's Disease based on encouraging data from 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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