Cyclo Therapeutics Inc. Announces Additional Efficacy Data from its Ongoing Phase I/II Trial using Trappsol® Cyclo™ Intravenously to Treat Patients with Niemann-Pick Disease Type C1 (NPC1)

GAINESVILLE, FL – (BusinessWire) – September 8, 2020 – Cyclo Therapeutics, Inc. (OTCQB: CTDH), a clinical stage biotechnology company that develops cyclodextrin-based products for the treatment of Niemann-Pick Disease Type C (NPC) and Alzheimer's Disease, today announced that 3 additional patients have completed the 48-week Phase I/II study. Results show encouraging trends in efficacy, consistent with findings of the first four patients who completed the study, as reported in the company's Interim Analysis in May 2020.

The group data show that six of the seven patients (86% of those who completed) met the primary endpoint of the Phase I/II study, which was to achieve at least a one-point reduction in two or more of the 17-Domain NPC Clinical Severity Scale (CSS) measures. Domains in which improvement were seen varied from patient to patient, in keeping with the heterogeneous nature of the disease. Features that improved included swallowing, ambulation, ability to manage seizures, saccadic eye movements, fine motor skills and cognition. Patients whose overall NPC Severity Scores showed worsening still had areas of improvement, with only one patient who worsened without having a single domain of improvement.

Additionally, five of seven patients also improved in the Clinician's Global Impression of Improvement scale (CGI-I), a second primary outcome measure. Of the five patients (71% of those who completed), one improved very much; two were much improved; two were minimally improved. The other 2 patients remained unchanged. Per the treating physicians, no change in score or stabilization can be viewed as a positive outcome given the progressive nature of the disease.

"The data on these 3 additional patients provide valuable insights as we continue to collaborate with both the FDA and EMA on our global Phase III pivotal program", said Cyclo Therapeutics' Chairman and CEO, N. Scott Fine. "Of those 7 patients who have completed the study, 5 improved in at least one of the 5-Domain NPC Clinical Severity Scale (5D-NPC-CSS) measure. This measure of the five domains (Swallow, Fine Motor, Ambulation, Cognition and Speech) is determined by NPC families and their caregivers in collaboration with the FDA to be the most important for their quality of life."

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

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.

Investor/Media Contact:
Jeffrey L. Tate, Ph.D. COO
Cyclo Therapeutics, Inc.
jeff@cyclodex.com
+1 (386) 418-8060