Cyclo Therapeutics Announces Publication of Positive Data from Phase 2 Clinical Study of Trappsol® Cyclo™ for the Treatment of Niemann-Pick Disease Type C1

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– Data published in official journal of Molecular Genetics and Metabolism Reports:

- Evidence of a change in cholesterol homeostasis in peripheral organs and the brain after the initial infusion
- Trappsol® Cyclo™ was detected in the CSF
- Completers had an 88.9% improvement in at least two domains of the 17-Domain Niemann-Pick Type C1 Clinical Severity Scale (17D-NPC-CSS)
- Improvement in Scale Assessment and Rating of Ataxia (SARA) score for the mean score in 7 of 8 domains at Week 48 compared with baseline
- Demonstrated a favorable benefit-risk profile

GAINESVILLE, Fla. –

Cyclo Therapeutics, Inc. (Nasdaq: CYTH) ("Cyclo Therapeutics" or the "Company"), a clinical stage biotechnology company dedicated to developing life-changing medicines through science and innovation for patients and families living with diseases, today announced the publication of positive data from its Phase 1/2 clinical trial, which demonstrated promising safety and efficacy results for Trappsol® Cyclo™ in the treatment of Niemann-Pick Disease Type C1, a rare, genetic disease causing cholesterol accumulation in cells, leading to dysfunction of the liver, lung, spleen and brain and premature death. The manuscript titled, *"Long-term administration of intravenous Trappsol® Cyclo™ (HPβCD) results in clinical benefits and stabilization or slowing of disease progression in patients with Niemann-Pick Disease Type C1: Results of an international 48-week Phase I/II trial,"* were published in the official journal of Molecular Genetics and Metabolism Reports.

"The data seen to-date provide support for the capacity of Trappsol® Cyclo™ to alter the disease on a biochemical level, including in the central nervous system, and improve clinical signs and symptoms of NPC. In these Phase 2 data, all three doses of Trappsol® Cyclo™ were well-tolerated overall with efficacy across multiple clinical endpoints of intravenous (IV) administration of Trappsol® Cyclo™. I am pleased with the progress we've made and remain committed to exploring the potential of Trappsol® Cyclo™ as a potential life-changing medicine for the NPC community," commented Caroline Hastings, MD, author of the published manuscript, Chair of the Company's Phase 3 Trappsol® Cyclo™ Program Steering Committee and Global Principal Investigator for the Company's ongoing TransportNPC™ study evaluating Trappsol® Cyclo™ for the treatment of NPC.

Cyclo Therapeutics continues to advance enrollment in its ongoing pivotal Phase 3 study, TransportNPC™. The Phase 3 study intends to enroll approximately 93 pediatric and adult patients (age 3 years and older) with NPC1 and is now active in 12 countries. Enrollment is expected to be completed by the end of this year.

N. Scott Fine, Chief Executive Officer of Cyclo Therapeutics, commented, "We first provided this investigational therapy to address symptoms of NPC back in 2009. This was a compassionate use program begun in the US and several other countries. Our formal clinical study began in 2015 and our commitment to this community has only intensified. We look forward to completing enrollment and advancing this important program rapidly on behalf of this deserving community."

About the Phase 1/2 Trappsol® Cyclo™ Program

The Phase 1/2 randomized, double-blind, parallel group, 48-week study was to compare the pharmacokinetics of three different IV doses of Trappsol® Cyclo™ in pediatric and adult patients with NPC1 and to evaluate the efficacy and tolerability of three different dosages of Trappsol® Cyclo™ in patients with NPC1 after long term treatment. Twelve patients aged at least two years (2-39 years of age) with a confirmed diagnosis of NPC1 were randomized to receive one of three IV doses of Trappsol® Cyclo™ (1500 mg/kg, 2000 mg/kg, or 2500 mg/kg) every 2 weeks for 48 weeks. All patients received Trappsol® Cyclo™; there was no placebo or other control. Pharmacokinetic testing of plasma and cerebrospinal fluid (CSF) was at set times after the first infusion. Pharmacodynamic assessments included biomarkers of cholesterol metabolism (synthesis and breakdown products), N palmitoyl-O-phosphocholineserine (PPCS), and specific biomarkers of CSF neurodegeneration (including total Tau), CNS inflammation (glial fibrillary acidic protein [GFAP] and tumor necrosis factor α [TNFα]), CNS cholesterol metabolism (24S hydroxycholesterol) and inflammatory markers. Efficacy measures included clinical disease severity, neurologic symptoms, and clinical impressions of improvement. Safety assessment included physical examination, vital signs, clinical safety laboratory assessment and adverse events (AEs).

A total of nine patients completed the study, two in the 1500 mg/kg group, four in the 2000 mg/kg group and three in the 2500 mg/kg group. Three additional patients (all in the 1500 mg/kg group) discontinued the study for non-safety reasons. In five patients who underwent serial lumbar punctures, Trappsol® Cyclo™ was detected in the CSF. Of the nine patients who completed the study, eight (88.9%) improved in at least two domains of the 17-Domain Niemann-Pick disease Type C1-Clinical Severity Scale (17D-NPC-CSS), and six of these patients improved in at least one domain viewed by patients and their caregivers to be key to quality of life, namely, speech, swallow, fine and gross motor skills, and cognition. Of the nine patients who completed the study, seven were viewed by their treating physicians as having improved to some degree at the end of the study, and two remained stable; both outcomes are highly relevant in a progressive neurodegenerative disease. Some patients and families reported improvement in quality of life. Additionally, Treatment with Trappsol® Cyclo™ resulted in an improvement in the SARA mean score in 7 of 8 domains at Week 48 compared with baseline, with the most notable improvements in the domains of stance, gait, and fast alternating hand movements. Importantly, there was no overall worsening in any domain.

All three doses of Trappsol® Cyclo™ were well tolerated overall, with most treatment emergent adverse events transient, mild-to-moderate in nature, and considered by the site PIs to be not related to study drug.

Cyclo Therapeutics received Orphan Drug Designation for Trappsol® Cyclo™ to treat NPC1 in both the U.S. and EU and Fast Track and Rare Pediatric Disease Designations in the U.S. The Rare Pediatric Disease Designation is one of the chief requirements for sponsors to receive a Priority Review Voucher in the U.S. upon marketing authorization.

About Cyclo Therapeutics

Cyclo Therapeutics, Inc. is a clinical-stage biotechnology company dedicated to developing life-changing medicines through science and innovation for patients and families living with disease. The Company's Trappsol® Cyclo™, an orphan drug designated product in the United States and Europe, is the subject of four formal clinical trials for Niemann-Pick Disease Type C1, a rare and fatal genetic disease, (www.ClinicalTrials.gov NCT02939547, NCT02912793, NCT03893071 and NCT04860960). The Company is conducting a Phase 2b clinical trial using Trappsol® Cyclo™ intravenously in early Alzheimer's disease (NCT05607615)based on encouraging data from an Expanded Access program for 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, including, without limitation, statements regarding the satisfaction of closing conditions relating to the offering and the anticipated use of proceeds from the offering. 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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