Cyclo Therapeutics Appoints Caroline Hastings, M.D. as Global Principal Investigator for Ongoing TransportNPC™ Study Evaluating Trappsol® Cyclo™ for the Treatment of Niemann-Pick Disease

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– Dr. Hastings is a world-renowned Key Opinion Leader for Niemann-Pick Disease Type C1 and the first physician in the U.S. to use cyclodextrins for treatment in NPC, compassionate use

– Site activation ongoing and currently enrolling patients in pivotal Phase 3 study, TransportNPC™

– Data seen to-date provide support for the capacity of Trappsol® Cyclo™ to stabilize disease progression with home-based intravenous infusions in NPC and demonstrate acceptable safety profile of Trappsol® Cyclo™ administered intravenously for more than 2 years

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 appointment of Caroline Hastings, M.D. as Global Principal Investigator ("PI") for its pivotal Phase 3 study ("TransportNPC™"), which commenced in June 2021, evaluating Trappsol® Cyclo™, the Company's proprietary formulation of hydroxypropyl beta cyclodextrin, for the treatment of Niemann-Pick Disease Type C1 ("NPC"), a rare, progressive and fatal genetic disorder.

Dr. Caroline Hastings has been practicing in the field of Pediatric Hematology Oncology since 1992 and has served as the director of the fellowship program at the Children's Hospital & Research Center Oakland since 1996. She has devoted herself to her patients and to fostering education in this specialty. Her academic interests include tumors of the brain and spinal cord, relapsed acute lymphoblastic leukemia, and lysosomal storage diseases including Niemann Pick Type C disease. Dr. Hastings currently serves as the Pediatric hematologist oncologist, Director of Neuro-oncology, and Professor of Pediatrics at UCSF Benioff Children's Hospital Oakland and is an advisor to U.S. and Australian NPC Advocacy organizations and to physicians globally on NPC.

"Dr. Hastings is a key voice and advocate within the NPC community and has dedicated her clinical career to serving this community. We are honored to expand her role as our Global Principal Investigator for our pivotal study and help drive this important program forward toward potential approval. As a pioneer in intravenous administration of cyclodextrins for NPC treatment and with a wealth of knowledge and expertise, we believe she brings a great deal of value to not only this program, but to other investigators in the trial and the patient community," commented Lise Lund Kjems, MD, PhD, Chief Medical Officer of Cyclo Therapeutics.

As the Global Principal Investigator for the TransportNPC™ study, Dr Hastings will serve as the senior scientific and clinical expert for the trial, be a key resource for participating investigators and Cyclo Therapeutics, as well as provide clinical perspective in health authority interactions.

The Company's pivotal TransportNPC™ Phase 3 study is a randomized, double-blind, placebo-controlled, parallel group, multicenter study designed to evaluate the safety, tolerability, and efficacy of 2,000 mg/kg doses of Trappsol® Cyclo™ administered intravenously and standard of care (SOC), compared to placebo administered intravenously and SOC alone, in patients with NPC1. The Phase 3 study intends to enroll at least 93 pediatric (age 3 years and older) and adult patients with NPC1 in at least 23 study centers in 9 countries. Eligible patients will be randomized 2:1 to receive either Trappsol® Cyclo™ or a placebo. Randomization will not be constrained based on patient age, nor will patient enrollment be gated by patient age. The study duration is 96 weeks and includes an interim analysis at 48 weeks.

"Patients and families within the NPC community continue to be faced with significant unmet needs. The clinical data to date shows that Trappsol® Cyclo™ reaches the central nervous system (CNS) and positively affects CNS biomarkers, when given intravenously. This fuels my hope that these needs can be met. I am truly humbled to serve as Global PI for this potentially catalytic program for the NPC community. I am dedicated to advancing TransportNPC™ towards completion and Trappsol® Cyclo™ towards potential approval for the treatment of NPC," added Dr. Hastings, Global Principal Investigator for the TransportNPC™ trial and member of Cyclo Therapeutics' Scientific Advisory Board.

As previously announced, the Company also received a positive opinion from the Paediatric Committee (PDCO) of the EMA and agreement on its Paediatric Investigation Plan (PIP) for Trappsol® Cyclo™. The PIP opinion from PDCO endorsed the clinical program to evaluate the safety, tolerability and efficacy of Trappsol® Cyclo™ in patients from 3 to less than 18 years of age with NPC in the randomized study, and in addition, to include a single-arm open-label sub-study of patients from birth to less than 3 years of age with NPC Type C1 irrespective of symptoms to evaluate safety and to obtain descriptive data on global disease severity and the response to Trappsol® Cyclo™. The sub-study in patients from birth to less than 3 years of age will only be conducted in the EU and countries following EMA guidelines.

For more information about the Company's TransportNPC™ pivotal Phase 3 study visit www.ClinicalTrials.gov and reference identifier NCT04860960.

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 suffering from 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 C, a rare and fatal genetic disease, (www.ClinicalTrials.gov NCT02939547, NCT02912793, NCT03893071 and NCT04860960). 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, 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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