Cyclo Therapeutics Achieves Landmark Milestone with Completion of Enrollment of Last Patient in Phase 3 Pivotal TransportNPC™ Trial of Niemann-Pick Type C1

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TransportNPC™ is the most comprehensive ongoing controlled pivotal study regarding patient size, global footprint, duration and clinical outcomes for the treatment of Niemann-Pick Disease Type C1 (NPC1)

Topline data from the 48-week interim analysis of 104 enrolled patients is anticipated for H1 2025

If 48-week data demonstrate significance, submission of New Drug Application (NDA) to the Food and Drug Administration (FDA) and Marketing Authorization Application (MAA) to European Medicines Agency (EMA) is targeted for 2H 2025; Qualification for Priority Review Voucher (PRV) upon NDA submission

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 last patient has been enrolled in the Company's pivotal Phase 3 study ("TransportNPC™") evaluating Trappsol® Cyclo™ for the treatment of systemic and neurological symptoms of Niemann-Pick Disease Type C1 (NPC1).

The TransportNPC™ study is the most comprehensive controlled pivotal study regarding patient size, global footprint, duration and clinical outcomes of an investigational therapy for NPC1. The study has dosed its 93rd (final) and 94th (over enrolled) patients. Additionally, the Company has enrolled ten (10) patients in its substudy per their adopted Paediatric Investigational Plan (PIP) treating newborn to 3 years of age. The substudy is evaluating Trappsol® Cyclo™ in the youngest age subsets as it targets also the visceral aspects of the disease and may achieve its most optimal results when administered early in the disease course, thus having the potential of a preventative effect in overall symptom development.

"The completion of enrollment represents by far the most significant milestone for Cyclo Therapeutics to date. Not only is this study the largest controlled pivotal study for NPC1 ever to be conducted with 104 patients enrolled, but we will also have approximately half of those 104 patients who completed the 96-week (two-year) timepoint at the time of our 48-week interim analysis, thus providing important additional long-term data supporting our potential submissions to the Health Authorities," commented N. Scott Fine, Chief Executive Officer of Cyclo Therapeutics. "With the positive support, feedback and alignment from our recent health authority interactions with both the FDA and EMA, we are excited to take this critical step toward the interim data readout, which is expected in H1 2025 and most importantly, the potential to provide a much-needed treatment option for the NPC community."

Professor Caroline Hastings, MD, Global Principal Investigator for the Company's ongoing TransportNPC™ study, added, "We are extremely pleased with the progress of this trial and to be a step closer to potentially providing a much-needed treatment option for this devastating disease that is in desperate need of a safe and effective approved

treatment for the systemic and neurological symptoms of NPC. Together with the global NPC community, we have steadily increased our understanding of NPC and Trappsol® Cyclo™ over the course of nearly two decades and look forward to the 48-week interim data readout in the first half of 2025. We believe this has the potential to provide a transformational impact for all people living with NPC and what this represents for this area of significant unmet need."

"We are grateful for the continued support of our investors, including Rafael Holdings, Inc. (RFL) and other longtime shareholders, who stand shoulder to shoulder with us to see the clinical development of Trappsol® Cyclo™ successfully cross the finish line," added Joshua Fine, Chief Financial Officer of the Company.

The Company's ongoing TransportNPC™ 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, a rare, genetic disease causing cholesterol accumulation in cells, leading to dysfunction of the liver, lung, spleen and brain and premature death. The study duration is a 96-week study, with a 48-week comparative interim analysis. Should the 48-week interim data meet statistical significance, the Company, in alignment with the FDA and EMA, intends to submit marketing applications for approval based on the 48-week interim data.

The Company's ongoing single-arm sub-study is evaluating patients from birth to less than 3 years of age with NPC1 irrespective of symptoms to evaluate safety and to obtain descriptive data on global disease severity and the response to Trappsol® Cyclo™. The substudy is being conducted in countries outside of the United States per their adopted PIP.

For more information about the Company's TransportNPC™ pivotal Phase 3 study, visit https://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 Niemann-Pick Disease Type C1 (NPC)

NPC is a rare genetic disease affecting 1 in 100,000 live births globally. Approximately 95% of individuals with NPC have mutations in the NPC1 gene and 5% have mutations in the NPC2 gene. NPC affects nearly every cell in the body due to a deficiency in either the NPC1 or NPC2 protein, which are required for the transport and processing of cholesterol within the cell. As cholesterol accumulates within cells, NPC causes symptoms that affect the brain, liver, spleen, lung, and other organs and often leads to premature death.

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: https://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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