

# Cyclo Therapeutics Provides Clinical Program Update and Highlights Recent Achievements

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- *Continued progress in ongoing pivotal Phase 3 global study (TransportNPC™) evaluating Trappsol® Cyclo™ for Niemann-Pick Disease Type C1 (NPC1) with 35% of expected enrollment completed, on track to complete enrollment by year end 2023*
- *Patient enrollment and dosing in Phase 2b study of Trappsol® Cyclo™ for the treatment of early Alzheimer's Disease (AD) underway*

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 provided updates for the Company’s Trappsol® Cyclo™ clinical program and provided a summary of key achievements in 2022, focused on our clinical portfolio of two neurodegenerative diseases with major unmet medical needs.

“We have continued to execute and make significant progress on our clinical programs evaluating Trappsol® Cyclo™ for the treatment of NPC and early Alzheimer’s disease. We recently announced the commencement of patient enrollment and dosing in our early AD clinical study and are dedicated to building momentum for that program. Additionally, we continue to make significant progress in our ongoing TransportNPC™ and remain on target to have the study completely enrolled by year end, a true testament to our team’s dedication, time, and effort. The Company has and will continue to focus the majority of its resources, both human and capital, to the NPC community and on advancing the TransportNPC™ study, an important area with significant unmet need,” commented N. Scott Fine, CEO of Cyclo Therapeutics. “We made noteworthy advancements in 2022 and are continuing to execute on all fronts. We look forward to an exciting year ahead.”

## **Trappsol® Cyclo™ Clinical Program Update**

Trappsol® Cyclo™ is the Company’s proprietary formulation of hydroxypropyl beta cyclodextrin, used intravenously (IV) and currently in development for the treatment of NPC, a rare genetic disorder causing cholesterol accumulation in lysosomes of cells, organ dysfunction and premature death, and early Alzheimer’s Disease (AD), where disrupted lipid pathways play a key role in the etiology and disease progression.

### *Niemann-Pick Disease Type C1 Development Program*

- Continued progress in patient enrollment with 35% in the ongoing TransportNPC™ study completed to-date and dosing ongoing across multiple regions;
- Announced the publication of Phase 1 data for Trappsol® Cyclo™ for the treatment of NPC in the official journal of the Society for Inherited Metabolic Disorders, Molecular Genetics and Metabolism;
- Attended the 2022 NPUK Annual Family Conference & Interactive Workshop on Niemann-Pick Disease with Caroline Hastings, M.D., Key Opinion Leader in NPC and Global Principal Investigator for the ongoing TransportNPC™ study, to connect with the global NPC community and discuss Trappsol® Cyclo™ and its clinical development program for the treatment of NPC;
- Announced the formation of Global Steering Committee comprised of leading experts to advise on the global Phase 3 clinical development program for Trappsol® Cyclo™ in NPC;
- Lise Kjems, MD, PhD and Chief Medical Officer, presented at the 2022 China Nieman Pick Medical Exchange & Sixth Patient Association, a physician, researcher and patient focused event to discuss NPC and the latest research results for diagnosis and treatment;
- Attended the NNPDA-INPDA Conferences 2022 with Caroline Hastings, M.D., Key Opinion Leader in NPC and Global Principal Investigator for the ongoing TransportNPC™ study, to discuss Trappsol® Cyclo™ and its clinical development program for the treatment of NPC;
- Provided an overview of the Trappsol® Cyclo™ program for the treatment of NPC at the World Orphan Drug Congress USA 2022 with Lise Kjems CMO as invited speaker
- Presence at World Symposium USA 2022 with Lise Kjems presenting TransportNPC study design and key considerations
- Presented an update on the results from Phase 1 and Phase ½ studies and launch of the international Phase 3 pivotal TransportNPC™ trial at the 2022 NPC Patient and Family Conference hosted by the Australian NPC Disease Foundation; and
- Dr. Kjems invited as speaker at BioFlorida 2022 Rare Disease Session.

For more information about the Company's Trappsol® Cyclo™ clinical program for the treatment of NPC1, visit [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) and reference identifiers [NCT02939547](https://clinicaltrials.gov/ct2/show/study/NCT02939547), [NCT02912793](https://clinicaltrials.gov/ct2/show/study/NCT02912793), [NCT03893071](https://clinicaltrials.gov/ct2/show/study/NCT03893071) and [NCT04860960](https://clinicaltrials.gov/ct2/show/study/NCT04860960).

### *Alzheimer's Disease Development Program*

- The ability of Trappsol® Cyclo™ to gain access to the CSF/brain and impact CSF tau and serum 24S-hydroxycholesterol when intravenously administered in NPC patients are very promising and represent a unique therapeutic development.
- Accelerated planning and start up phase for Phase 2b clinical trial
- Commenced and initiated patient enrollment and dosing in its Phase 2b study of Trappsol® Cyclo™ for the treatment of early AD, targeting the reduction of amyloid beta and tau.
- Accelerated planning and startup phase for Phase 2b clinical trial

With the biologic similarities demonstrated between Alzheimer's disease and Niemann-Pick disease Type C1 and, including cholesterol accumulation in regions of the brain, elevated levels of Tau in cerebrospinal fluid ("CSF"), and amyloid plaques in the brain, the Company believes Trappsol® Cyclo™ has significant potential to be an effective treatment option for Alzheimer's disease.

For more information about the Company's Trappsol® Cyclo™ clinical program for the treatment of early AD and Expanded Access program, visit [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) and reference identifiers [NCT05607615](#) and [NCT03624842](#), respectively.

### *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 C, a rare and fatal genetic disease, ([www.ClinicalTrials.gov](http://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](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, 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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