Cyclo Therapeutics Presents Positive Data from Clinical Development Program for Lead Candidate, Trappsol® Cyclo™, at WORLD*Symposium* 2021

Data from ongoing Phase 1 extension study shows improvement in disease features or disease stabilization with home-based intravenous infusions of Trappsol® Cyclo™

Phase 1 biomarker 24S-hydroxycholesterol demonstrates clearance of excess cholesterol from the brain after intravenous infusions

Interim analysis of Phase 1/2 study shows Trappsol® Cyclo™ to have favorable safety profile and encouraging signals in efficacy

Phase 1/2 study to be completed in February 2021 with topline results expected Q1 2021

Enrollment in pivotal Phase 3 study to commence in Q2 2021

Gainesville, FL – (Businesswire) – February 8, 2021 -- Cyclo Therapeutics, Inc. (Nasdaq: CYTH) ("Cyclo Therapeutics" or the "Company"), a clinical stage biotechnology company developing cyclodextrin-based products for the treatment of Niemann-Pick Disease Type C and Alzheimer's disease, today announced the presentation of favorable data from its clinical and drug development program for its lead candidate, Trappsol® Cyclo™. These data are being presented at the 17th Annual WORLD*Symposium* 2021, a leading medical and scientific conference for professionals working to advance understanding and treatments for lysosomal storage diseases, including Niemann-Pick Disease Type C ("NPC"), being held virtually February 8–12, 2021.

"These data continue to bolster our confidence in the potential of Trappsol® Cyclo™ to treat systemic and neurologic manifestations of NPC. With the continued safety and efficacy signals seen to-date, we remain committed to advancing this program swiftly in order to address the significant unmet need and importantly, provide hope for patients and their families. We are immensely grateful to the patients, families and treating physicians who have and continue to participate in these studies," said Sharon Hrynkow, PhD, the Company's Chief Scientific Officer and Senior Vice President for Medical Affairs. "We look forward to topline data readout from our Phase 1/2 study this quarter and commencing enrollment in our pivotal Phase 3 study."

Trappsol® Cyclo™, Cyclo Therapeutics' proprietary formulation of hydroxypropyl beta cyclodextrin, used intravenously (IV), is currently in development for the treatment of NPC1, a rare genetic disorder causing cholesterol accumulation in lysosomes of cells,

organ dysfunction and premature death. Functioning like the NPC1 protein, Trappsol® Cyclo™ has been shown to transport cholesterol out of cells, normalizing cholesterol metabolism. Following review of the Phase 1 and Phase 1/2 data, coupled with preclinical compassionate use data, regulatory authorities acknowledged that IV hydroxypropyl beta cyclodextrin has the potential to treat systemic and neurologic manifestations of NPC, and has the capacity when given intravenously to be a preventative treatment. The Company has confirmation that the pivotal Phase 3 study may begin enrollment.

Ongoing Phase 1/2 Safety and Efficacy Results

The Phase 1/2 trial of Trappsol® Cyclo ™, evaluates 3 dose groups (1500, 2000, 2500 mg/kg) administered intravenously (IV) in NPC patients aged 2-plus bi-weekly over 48 weeks. Enrollment of 12 patients was completed in February 2020. Last patient last visit for the study is expected in February 2021. An interim unblinded analysis occurred in May 2020. To-date, individual and cumulative safety data show the drug to be well tolerated with a favorable safety profile for all dose groups.

Previously reported data show effects of IV drug administration on markers of cholesterol synthesis and metabolism. Pharmacokinetic data show the drug in cerebrospinal fluid during and even after the end of IV infusion, at all dose levels. Lysosphingomyelin-509 in plasma demonstrates a clear downward trend over the 48-week study, with no apparent dose-relationship, further supporting the drug's ability to clear lipids from lysosomes. Tau, a biomarker of neurodegeneration, is reduced in cerebrospinal fluid of patients who opted for lumbar punctures at 24 and 48 weeks, suggesting a neuroprotective effect of the drug. For the 7 patients who completed the trial as of September 2020, 6 (86%) met the first efficacy criterion of the study related to improvement in 2 domains of the 17-domain Severity Scale. For the second efficacy outcome measure, change from baseline in global impression of disease, 5 of 7 patients improved per the Clinicians Global Impression of Improvement scale and 2 were stabilized.

Julian Raiman, MD, Birmingham Women's and Children's Hospital, United Kingdom and Principal Investigator for the Phase 1/2 study added, "There remains a significant unmet need for NPC patients, families and treating physicians. We continue to be encouraged by the trend toward improvement we have seen in the study thus far with intravenous hydroxypropyl beta cyclodextrin and look forward to the completion and topline data readout in the coming weeks."

Completed Phase 1 Study Results and the Effects of Dosing Upon Biomarkers of NPC Disease

The Phase 1 study of Trappsol® Cyclo ™ in NPC1 patients was randomized, double-blinded, with no control group (NCT02939547). Patients 18 years-plus received either 1500 or 2500 mg/kg of drug intravenously (IV) over 8-9 hours bi-weekly for 7 doses. Individual and cumulative safety data show both dose levels to have a favorable safety profile, although the 2500 mg/kg group included 3 serious adverse events related to transient hearing loss. Pharmacokinetic findings show Tmax of 6-8 hours with T ½ of 2

hours. The drug is detectable in cerebrospinal fluid (CSF) at 4 hours after start of infusion and persists up to 4 hours post-infusion. IV treatment impacts cholesterol homeostasis as evidenced by transient increases in total cholesterol levels; serum markers of cholesterol synthesis and metabolism; and liver biopsy data showing significant cholesterol clearance for both doses. Lysosphingomyelin-509 decreases significantly in most patients with successive infusions. Plasma biomarkers of inflammation, including lysozyme, show a general decrease. Effects within the CNS are shown by the CSF biomarker tau which is reduced in 6 of 10 patients as compared to baseline, suggesting a neuroprotective effect, and a serum increase of a CNS-derived metabolite of cholesterol, 24S-hydroxycholesterol. Three patients improved in Swallow and 1 worsened in Cognition as measured by the 17-domain NPC Severity Scale.

After individual doses and at trial end some patients reported feeling more focused, more engaged in social interactions; more likely to initiate conversations or activities; word finding ability reaching back into the past; improvements in ability to swallow without coughing; and improvements in stance and gait.

All 8 eligible patients (U.S. residents) enrolled in the Extension Protocol, receiving infusions in the home setting. Initial efficacy evaluation in September 2020 showed disease stabilization with notable clinical improvements in some patients.

These findings confirm target engagement with a positive impact on cholesterol metabolism and liver cholesterol clearance in patients with NPC1 supporting continued evaluation of Trappsol® Cyclo™ as a therapeutic for NPC1.

The oral poster presentations are now available on the Company's website in the Presentations section.

About WORLDSymposium™

WORLD*Symposium*™ is an annual research conference dedicated to lysosomal diseases. WORLD is an acronym that stands for We're Organizing Research on Lysosomal Diseases. Since its inception as a small group of passionate researchers in 2002, WORLD*Symposium* has grown to an international research conference that attracts over 2000 participants from more than 50 countries around the globe. For more information, please visit: worldsymposia.org.

About Niemann-Pick Disease Type C

Niemann-Pick Disease Type C1 is a rare genetic disease affecting 1 in 100,000 live births globally. NPC1 affects every cell in the body due to a defect in the NPC1 protein which is responsible for cholesterol processing in the cell. NPC causes symptoms in the brain, liver, spleen, lung and other organs and often leads to premature death. There are no approved drug therapies for NPC in the United States and only one approved therapy in Europe.

About Cyclo Therapeutics, Inc.

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 NCT02912793). 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.

Investor Contact:

JTC Team, LLC
Jenene Thomas
(833) 475-8247
CYTH@jtcir.com