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Cyclo Therapeutics to Proceed with IND Filing for Phase 2 Trial Using Intravenous Trappsol® Cyclo™ in Alzheimer's Disease

FDA feedback supports Company's Phase 2 development strategy for Alzheimer's disease asset; IND filing on track for H2 2021

GAINESVILLE, Fla.--(BUSINESS WIRE)-- 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 suffering from diseases, today announced that it has received feedback from the U.S. Food and Drug Administration ("FDA") supporting the Company's development strategy to submit an initial new drug application ("IND") application for a Phase 2 study of Trappsol® Cyclo™ in the treatment of early Alzheimer's disease, following a positive Type B interaction.

"We are encouraged by the feedback and recommendations from the FDA and are grateful for their support of our proposed Phase 2 development strategy for Trappsol® Cyclo™ in the treatment of Alzheimer's disease. This interaction was an important step forward for our Alzheimer's disease program as we move forward with the filing of our initial IND. We are looking forward to supporting the advancement of this asset and the potential to bring an important treatment option to patients," commented Michael Lisjak, Chief Regulatory Officer, Senior Vice President for Business Development of Cyclo Therapeutics.

The Company is currently advancing its lead product candidate of Trappsol® Cyclo™ in a pivotal Phase 3 study for the treatment of Niemann-Pick Type C (NPC1), expected to commence this quarter. Cyclo Therapeutics' Alzheimer's disease program is the second pipeline candidate program generated from the Company's platform technology. The Company is on track to file its IND for a Phase 2 study of Alzheimer's disease in the second half of this year.

N. Scott Fine, CEO of the Company added, "The Cyclo Therapeutics team continues to make fundamental progress on all fronts, and I am very pleased with the outcome of our FDA interaction. We believe our Alzheimer's disease asset has potential as a disease modifying treatment and look forward to identifying the best strategic partner to advance this important program. Our focus and priority remain on advancing our pivotal Phase 3 study of Trappsol® Cyclo™ towards approval to address the needs of the NPC community."

As previously announced, the Company filed an international patent application titled "Methods for Treating Alzheimer's Disease," published as International Publication Number: WO 2020/092107 Al.

About Alzheimer's Disease

Alzheimer's disease is a progressive neurologic disorder that causes the brain to shrink (atrophy) and brain cells to die. Estimates vary, but experts suggest that more than 5.5 million Americans, most of them age 65 or older, may have dementia caused by Alzheimer's. Most people with Alzheimer's have the late-onset form of the disease, in which symptoms become apparent in their mid-60s. Early-onset Alzheimer's disease occurs between a person's 30s and mid-60s and represents less than 10 percent of all people with Alzheimer's. The early signs of the disease include forgetting recent events or conversations. As the disease progresses, a person with Alzheimer's disease will develop severe memory and thinking skills impairment, then lose ability to learn, reason, make judgments, communicate and carry out daily activities. Medications may temporarily improve or slow progression of symptoms, however there is currently no treatment that cures Alzheimer's disease or alters the disease process in the brain.

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 three ongoing formal clinical trials for Niemann-Pick Disease Type C, a rare and fatal genetic disease, (ClinicalTrials.gov NCT02939547, NCT02912793 and NCT03893071). 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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