

Cyclo Therapeutics, Inc. to Present Clinical Trial Data on Niemann-Pick type C Disease at the 16th Annual WORLDSymposium

Data show that Trappsol® Cyclo™, the Company's proprietary hydroxypropyl beta cyclodextrin drug, reduces levels of trapped cholesterol in liver tissue of Niemann-Pick Disease Type C Patients

GAINESVILLE, FL – (Businesswire) – December 16, 2019 – Cyclo Therapeutics, Inc. (OTCQB: CTDH), a clinical-stage biotechnology company that develops cyclodextrin-based products for the treatment of Niemann-Pick Disease Type C (NPC) and Alzheimer's Disease, today announced its presentation at the WORLDSymposium ("We're Organizing Research on Lysosomal Diseases") to be held in Orlando, Florida, between February 10-13, 2020. The presentation is entitled, "Trappsol® Cyclo™ hydroxypropyl beta cyclodextrin administered intravenously in patients with Niemann-Pick Disease Type C reduces cholesterol in liver tissue." The presentation includes data from the Company's ongoing Phase I clinical trial in the United States to evaluate Trappsol® Cyclo™ administered intravenously in NPC in subjects 18 years and older (see ClinicalTrials.gov [NCT02939547](https://clinicaltrials.gov/ct2/show/study/NCT02939547) for study parameters).

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

Co-authors of the presentation are the two Co-Principal Investigators of the Phase I trial, Caroline Hastings, MD, UCSF Benioff Children's Hospital Oakland, and Benny Liu, MD, also affiliated with UCSF Benioff Children's Hospital Oakland for this trial and the Alameda Health System also in Oakland, joined by Bryan Hurst, MPhil of Boyd Consultants, UK, and Cyclo Therapeutics' Chief Scientific Officer and Senior Vice President for Medical Affairs Sharon Hrynkow PhD.

The presentation includes liver biopsy data from the first 8 subjects participating in the Phase I trial. Specifically, liver biopsy tissue was stained with a fluorescent marker, filipin, which binds unesterified cholesterol, in liver cells of study subjects both at baseline and after 7 doses of Trappsol® Cyclo™. Dosing is every two weeks with an approximate 8 hour infusion of the study drug. All subjects receive the study drug at either 1500 mg/kg body weight or 2500 mg/kg body weight. Results show that filipin staining in liver tissue in 5 of 8 subjects had marked reductions in filipin staining after 7 doses of Trappsol® Cyclo™, 2 had moderate reductions, and 1 had a mild reduction as compared to baseline. These are the first results showing that Trappsol® Cyclo™, or any hydroxypropyl beta cyclodextrin product, reduces unesterified cholesterol accumulation in liver tissue of NPC patients. These results are consistent with the Company's previously presented biochemical data showing that Trappsol® Cyclo™ decreases cholesterol synthesis and increases cholesterol metabolism (WORLDSymposium presentation, 2019). A more complete interpretation of the present data will be possible at study unblinding in early

2020. The presentation abstract is available on the Cyclo Therapeutics' website at: www.cyclotherapeutics.com

The details for Cyclo Therapeutics' presentation are as follows:

Date: Wednesday, February 12, 2020

Time: 4:30 pm to 6:30 pm/Latebreaking Poster Session; Poster LB-18

Place: Hyatt Regency, Orlando, Florida

In addition to the Phase I trial, Cyclo Therapeutics' supports a Phase I/II trial in NPC also using Trappsol® Cyclo™ administered intravenously. The Phase I/II trial is nearing completion of enrollment. Cyclo Therapeutics has submitted a Type C Meeting Request with the FDA and expects to meet with FDA in early 2020 to discuss the proposed development plan for a Phase III pivotal trial using Trappsol® Cyclo™ intravenously in NPC patients.

About Cyclo Therapeutics:

Cyclo Therapeutics, Inc. is a clinical-stage biotechnology company that develops cyclodextrin-based products for the treatment of disease. The company's Trappsol® Cyclo™, an orphan drug designated product in the United States and Europe, is in three ongoing formal clinical trials for Niemann-Pick Disease Type C, a rare and fatal genetic disease (ClinicalTrials.gov [NCT02939547](https://clinicaltrials.gov/ct2/show/study/NCT02939547), [NCT02912793](https://clinicaltrials.gov/ct2/show/study/NCT02912793) and [NCT03893071](https://clinicaltrials.gov/ct2/show/study/NCT03893071)), and in an Expanded Access program for late-onset Alzheimer's Disease ([NCT03624842](https://clinicaltrials.gov/ct2/show/study/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. 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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