July 9, 2020

Cyclo Therapeutics Announces Presentations on Phase I and Phase I/II Trials using Trappsol® Cyclo™ Intravenously to Treat Patients with Niemann-Pick Disease Type C1 at National Niemann Pick Disease Foundation Family Support and Medical Conference

The Company is also a proud supporter of the NNPDF Conference for the 5th year

GAINESVILLE, Fla.--(BUSINESS WIRE)-- Cyclo Therapeutics, Inc. (OTCQB: CTDH), a clinical-stage biotechnology company that develops cyclodextrin-based products for the treatment of Niemann-Pick Disease Type C1 (NPC1) and Alzheimer's Disease, today announced that two of the treating clinicians who lead clinical sites in the Company's ongoing clinical trials will present data on behalf of the Company at the annual Family Support and Medical Conference convened by the National Niemann-Pick Disease Foundation (NNPDF). NNPDF is a non-profit organization dedicated to supporting Niemann Pick patients and families in the United States. The Conference will be held virtually between July 10 – 12, 2020.

"Cyclo Therapeutics is excited to have the opportunity to share data from our Phase I trial and Phase I/II trial with the entire NPC community, and especially the patients, caregivers, scientists and physicians who are working together to find treatments and a cure," said N. Scott Fine, the Company's Chairman and CEO. "The presentations show a favorable safety profile of our drug, Trappsol® Cyclo™, in NPC patients as well encouraging trends in efficacy. Based on these data, we are working with regulators to design and launch our global Phase III pivotal trial by the end of 2020. This is a wonderful moment for all of our stakeholders and supporters, and for the NPC community broadly."

Niemann-Pick Disease Type C is a rare and often fatal genetic disease which damages the brain, liver, lungs and spleen due to overaccumulation of cholesterol in cells. There are no approved therapeutics for NPC in the United States.

"Our Conference is an important annual event which connects families to one another and brings the latest updates from pharmaceutical industry partners working to advance the science and treatment of Niemann-Pick disease. The collaboration of industry and families is vital to bringing medicines to market and to meeting the urgent needs of this devastating disease," said Joslyn Crowe, Executive Director of NNPDF.

The presentations describe top line results from the Phase I trial, which is now closed, and interim results from the Phase I/II trial which is expected to be completed in early 2021. The Company provided a similar presentation to the investor community in May 2020.

Presentations will take place on Saturday, July 11, 2020, between 1:15 pm and 1:45 pm:

- Caroline Hastings, MD, UCSF Benioff Children's Hospital, Oakland, CA, "Top Line Results of Phase I Intravenous Trial for NPC," and,
- Julian Raiman, MD, Birmingham Children's Hospital, UK, "Interim Analysis of Phase I/II Trial with Trappsol® Cyclo™ Delivered Intravenously in NPC Patients."

A Q & A period will follow the presentations and will include N. Scott Fine, Company Chairman and CEO, and Sharon Hrynkow, Ph.D., Chief Scientific Officer and Senior Vice President for Medical Affairs.

As part of this year's virtual conference program, NNPDF hosted a platform for industry representatives to meet with NPC patients and families on June 28, 2020.

"We are grateful to NNPDF for arranging the opportunity for us to hear directly from NPC patients and families about their diagnostic journeys and their day-to-day challenges while living with NPC," said Dr. Sharon Hrynkow. "As we finalize the design our Phase III trial, such opportunities provide us the kinds of insights that will ensure that our trial design meets the needs of the patients that we are working so hard to help."

The presentations to be made on July 11, 2020 may be found HERE.

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:

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 formal clinical trials for Niemann-Pick Disease Type C, a rare and often 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. 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.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20200709005730/en/

Investor/Media Contact:
Jeffrey L. Tate, Ph.D., COO
Cyclo Therapeutics, Inc.
jeff@cyclodex.com

Source: Cyclo Therapeutics, Inc.