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Cyclo Therapeutics Announces Its Support for The Firefly Fund's Newborn Screening Program

Announcement Made in Conjunction With October 19th Global Awareness Day for Niemann-Pick Disease Sponsored by International Niemann Pick Disease Alliance

GAINESVILLE, Fla.--(BUSINESS WIRE)-- Cyclo Therapeutics, Inc. (OTCQB:CTDH), formerly CTD Holdings, Inc., a biotechnology company that develops cyclodextrin-based products for the treatment of disease, today announced that the company has provided a grant to The Firefly Fund in support of its newborn screening program for Niemann-Pick Disease Type C.

"We are proud to support The Firefly Fund and its important work in newborn screening," said N. Scott Fine, Company Chairman and CEO. "It is our hope that screening for NPC will someday be available globally so that affected families can receive as much help as possible and as soon as possible. We applaud The Firefly Fund for working toward that goal."

Niemann-Pick Type C Disease (NPC) is a rare and 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. NPC causes 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 approved therapy in Europe.

In June 2017 the Firefly Fund convened a national multi-disciplinary working group that is representative of various community and industry NPC stakeholders who all share a common vision: to add NPC to state and federal newborn screening lists. Pam Crowley Andrews, Co-Founder and Executive Director of The Firefly Fund explained her strategy for seeking a successful nomination to the Federal Recommended Uniform Screening Panel (RUSP), which is a federal list that states use as a guidepost for adding conditions to the various state lists. Ms Andrews explained, "**We are building a broad and diverse coalition that is representative of the entire NPC Community. When we began our work, we had one industry partner supporting this initiative and today we have about 10 industry partners, all working on the development of different NPC therapies, that are supporting our newborn screening Initiative. It's an "All Hands on Deck" approach to this important work that I believe will ultimately be disease-modifying. Knowing earlier about the health status of your child allows parents the option, with guidance from their doctor, to intervene earlier. My husband, Chris Andrews, and I were given the option to intervene early in our younger daughter, Abby, following her diagnosis at 18 months old, before any visible signs or symptoms of the disease. It has now**

been 3 ½ years since our girls were diagnosed with NPC and our younger daughter is thriving with very few clinical symptoms of NPC. She is an active and neurotypical 5 year old little girl who speaks two languages fluently and enjoys her gymnastics, ballet and knitting classes with her friends. Big sister, Belle (9yo) is so proud of Abby who was just cast in the Nutcracker, which Abby will perform in this December in a theatre in Austin, Texas, with her peers. My husband and I envision a day where all babies born in the United States will be screened for and diagnosed with NPC before any visible signs or symptoms of the disease. We believe that this will be key to rendering Niemann Pick Type C a chronic disease. Newborn Screening is a big and important piece of the NPC puzzle.”

Recently Firefly Fund announced the launch of a pilot study of newborn screening for NPC in New York state, referred to as New York Screen Plus, where families will have the option to screen for 13 Lysosomal Storage Diseases (LSDs) in addition to what is already on the state's newborn screening list. This pilot study, under the leadership of Dr. Melissa Wasserstein, will screen approximately 200,000 newborns at 8 different hospitals for 13 LSDs, including NPC, over the course of the next five years. Ms. Andrews said, ***“When this historic program launches in a few months, it will be the first time any newborn born anywhere in the world will be screened for NPC. Through this study, we plan to collect the evidence necessary to support what NPC expert clinicians already believe — that early diagnosis and intervention for NPC patients improves health outcomes. This study will also give us an opportunity to learn more about how NPC can fit into our existing public health infrastructure.***

“We are thrilled to have Cyclo Therapeutics, Inc. join our wonderful group of NPC Stakeholders as an Industry Partner supporting Firefly Fund’s NPC Newborn Screening Initiative. It is important that all NPC stakeholders support this project, and not just financially, but in spirit too. It strengthens our message and the quality of our work when we come together as a community and show decision makers that we have consensus among all NPC stakeholders on this important topic of newborn screening,” said Ms. Andrews.

Cyclo Therapeutics’ support for The Firefly Fund is part of its broader effort to support the NPC community while its drug development program for NPC advances. The company currently supports clinical trials for its proprietary hydroxypropyl betacyclodextrin drug, Trappsol® Cyclo™, with sites in the United States, United Kingdom, Sweden and Israel. In addition to its new support for The Firefly Fund, Cyclo Therapeutics' support has included an array of organizations that assist patients and families with NPC, and scientists and physicians working on NPC. These include the International Niemann Pick Disease Alliance (INPDA), the National Niemann Pick Disease Foundation (USA), Niemann Pick UK, and the Australia’s Niemann Pick Disease Association. Cyclo Therapeutics is additionally an industry member of the International Niemann-Pick Disease Registry, a joint initiative between patient organizations and clinicians involved in the care of people with Niemann Pick disease focused on increasing understanding of the disease and speeding potential treatments on their development path.

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, (Clinical Trials.gov [NCT02939547](#), [NCT02912793](#) and [NCT03893071](#)) and in 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

About The Firefly Fund:

The Firefly Fund, launched on World Rare Disease Day in 2017, is a non-profit organization headquartered in Austin, Texas, with a mission to fund and support the research and education necessary to accelerate a cure for rare genetic neurodegenerative diseases that effect children and have no cure. There are three programs that are the core of what the Firefly Fund is doing for the NPC Community; (1) funding for translational Medical Research; (2) NPC Newborn Screening Initiative; (3) Patient Access Fund. www.firefly.fund

About the International Niemann Pick Disease Alliance:

The International Niemann Pick Disease Alliance (INPDA) is a global network of non-profit organizations, supporting persons affected by Niemann Pick Diseases (NPD). The alliance was formed in 2009 to provide a forum for patient groups and professionals working in the field of NPD.

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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RedChip Companies, Inc.
Victor Roberts, 407-571-0909
victor@redchip.com

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