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CTD Announces New Expanded Access Program in Taiwan using Trappsol Cyclo for Niemann-Pick Disease type C

Program is open to two patients who completed CTD's clinical trial with Trappsol® Cyclo™ in the United States

ALACHUA, FL / ACCESSWIRE / May 7, 2019 /CTD Holdings, Inc. (OTCQB: CTDH), a clinical stage biotechnology company that develops cyclodextrin-based products for the treatment of disease with unmet medical need, today announced that two patients from Taiwan who completed CTD's Phase I clinical trial using Trappsol® Cyclo™, the company's proprietary formulation of hydroxypropyl beta cyclodextrin, will continue to have access to the drug through an approved expanded access program in Taiwan. The US trial is "A Phase I Study to Evaluate the Single- and Multiple-Dose Pharmacokinetics of Intravenous Trappsol® Cyclo™ in Patients with Niemann-Pick Disease Type C and the Effects of Dosing Upon Biomarkers of NPC Disease" (NCT02939547).

The program is a collaboration between CTD Holdings, Inc., the Taiwan Foundation for Rare Disorders, and the National Taiwan University Hospital.

CTD's Chairman and CEO N. Scott Fine said, "We are pleased to provide continued access to Trappsol® Cyclo™ to these patients, and we are so grateful to them and to their families for their participation and support of our US trial."

"Expanded access programs such as the one underway through CTD Holdings and our hospital provide NPC patients with continued access to drugs still in the development pathway. We believe that continued access will benefit not only these patients, but also all NPC patients who will benefit once the drug is ultimately approved by the regulatory authorities," said Dr. Wuh-Liang Hwu, Professor, Department of Pediatrics, National Taiwan University Hospital.

NPC is a rare and fatal genetic disease characterized by the accumulation of cholesterol in cells and tissues. There are no approved drug therapies in the United States. The standard of care is treatment of disease manifestations, which range from seizures, loss of muscle tone, difficulty in speaking and swallowing, problems in walking and coordinating movements, and cognitive decline. As reported at two clinical and scientific conferences earlier this year, initial data from CTD's Phase I trial and a companion trial in Europe and Israel (NCT02912793) show that Trappsol® Cyclo™ has a positive safety profile, that intravenous administration of the drug leads to cholesterol release from cells, and that Trappsol® Cyclo ™ crosses the blood-brain-barrier.

"Initial efficacy data from both the US trial and the Europe/Israel trial are encouraging," said Sharon Hrynkow Ph.D., CTD's Chief Scientific Officer and Senior Vice President for Medical Affairs.

The two hospital sites participating the Phase I trial are UCSF Benioff Children's Hospital Oakland, California, led by Caroline Hastings, M. and Benny Liu, MD, and Morristown Medical Center of the Atlantic Health System, New Jersey, led by Darius Adams, MD. Enrollment for CTD's US Phase I trial is nearing completion. Interested patients and their caregivers should contact CTD Family Liaison Shannon Reedy at Shannon.Reedy@hotmail.com, Dr. Hastings at chastings@mail.cho.org for the Oakland, CA site or Dr. Adams atdarius.adams@atlantichealth.org for the Morristown, NJ site.

About CTD Holdings:

CTD Holdings, 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 used to treat Niemann-Pick Disease Type C, a rare and fatal genetic disease, on a compassionate use basis as well as in three ongoing formal clinical trials (Clinical Trials.gov NCT02939547, NCT02912793 and NCT03893071). Additional indications for the active ingredient in Trappsol® Cyclo™ are in development. For additional information, visit the company's website: www.ctd-holdings.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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