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CTD Holdings Announces FDA Approval of US Expanded Access Treatment Program in Niemann-Pick Disease Type C

ALACHUA, Fla.--(BUSINESS WIRE)-- 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 the company will provide Trappsol[®] Cyclo[™], its proprietary hydroxypropyl beta cyclodextrin drug, to a pediatric patient diagnosed with Niemann-Pick Disease Type C. The company received notice today of the FDA approval of the individual IND application from the treating physician, Caroline Hastings, MD, pediatric hematologist/oncologist at the UCSF Benioff Children's Hospital in Oakland, CA.

CTD's Chairman and CEO, N. Scott Fine, said, "CTD was the first to provide cyclodextrins for use in NPC patients on an expanded access basis in the United States, this was in 2009. We are pleased to once again offer our product for intravenous administration to this pediatric patient on an expanded access basis, even as we advance our formal clinical trials for registration of the drug for the NPC indication."

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. Because of the NPC defect in this disease, cholesterol accumulates abnormally 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.

CTD is currently developing Trappsol[®] Cyclo[™] as a treatment for NPC in 2 main clinical trials, one based in the United States (a Phase I study) and one based in Europe and Israel (a Phase I/II study). Both trials are nearing completion of enrollment, and design of the pivotal trial is underway. Dr. Hastings serves as the Co-Principal Investigator for the Phase I study in the US in addition to her role as Senior Clinical Advisor to the Phase I/II study. She is also the first physician in the US to administer cyclodextrins (CTD's product) to NPC patients on an expanded access basis.

"For patients who are not eligible for ongoing clinical trials, expanded access programs such as this one are a critical means for them to receive experimental therapies," said Dr. Hastings.

CTD's Chief Scientific Officer and Senior Vice President for Medical Affairs Sharon Hrynkow PhD added, "We have learned a great deal about Trappsol[®] Cyclo[™] in NPC through

expanded access programs over the years: the positive safety and tolerability profile when the drug is administered intravenously coupled with the neurologic and systemic benefits as observed in multiple patients and by multiple physicians show the value of these kinds of programs for patients and for CTD.”

Dr. Hrynkow and Dr. Hastings have presented at several scientific and medical conferences on the outcomes of CTD’s longstanding expanded access programs globally using Trappsol[®] Cyclo[™] by intravenous administration in NPC patients. Data from the company’s expanded access programs formed the basis of the clinical trial applications for the current trials underway in the US, Sweden, Israel and the United Kingdom. See ClinicalTrials.gov for more information on CTD’s ongoing trials [NCT02939547](#), [NCT02912793](#) and [NCT03893071](#), and CTD’s website for company presentations www.ctd-holdings.com.

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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