

FDA Authorizes CTD to Proceed with Extension Protocol to US Phase I Trappsol(R) Cyclo(TM) Trial for Niemann-Pick Disease Type C

ALACHUA, FL -- (Marketwired) -- 04/30/18 -- 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 FDA has authorized its application for "An Open-Label Extension Study of the Long-Term Safety and Efficacy of Intravenous Trappsol® Cyclo™ (HPBCD) in Patients with Niemann-Pick disease type C (NPC-1)" to proceed and states there are no safety concerns.

"The study will allow CTD's Trappsol® Cyclo™ to be administered to eligible patients who have completed CTD's Phase I study to evaluate single and multiple dose pharmacokinetics of intravenously administered Trappsol® Cyclo™", said N. Scott Fine, Chairman and CEO, CTD Holdings, Inc. "Continued access to our drug through this extension study will allow us to further evaluate the long-term benefits and safety of Trappsol® Cyclo™ in those suffering from NPC. As our company works toward market registration of Trappsol® Cyclo™, this study is expected to provided key insights."

The Extension Study will be led by Dr. Caroline Hastings, pediatric hematologist/oncologist at UCSF's Benioff Children's Hospital Oakland, California. Dr. Hastings is also the Principal Investigator for the Phase I trial.

"Trial participants who have received Trappsol® Cyclo™ and who meet eligibility requirements will be afforded an important opportunity to continue receiving the drug," said Dr. Hastings. "The decision by CTD to support an extension protocol while formal trials for market registration are still ongoing shows an enormous commitment from the company."

CTD's proprietary formulation of hydroxypropyl beta cyclodextrin, Trappsol® Cyclo™ is currently being evaluated in the Phase I study centered in the US, as well as in a Phase I/II study centered in the UK, Sweden and Israel. NPC is a rare genetic disease that causes neurologic, liver, lung and other organ dysfunction and that is ultimately fatal.

"CTD's commitment to the NPC community is clear. With this extension study, we expand our clinical program as we work to find new treatment options for this rare and devastating disease," said Sharon Hrynkow, PhD, CTD's Senior Vice President for Medical Affairs.

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 and is the subject of two ongoing clinical trials. 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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