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CTD Holdings Announces Plans to Broaden its Expanded Access Program for Trappsol® Cyclo™

Company expects to provide its drug to new patients in early 2019

ALACHUA, Fla., Oct. 15, 2018 (GLOBE NEWSWIRE) -- CTD Holdings, Inc. (OTCQB: CTDH), a clinical stage biotechnology company that develops cyclodextrin-based products for the treatment of disease with unmet medical need, announced today that the company will broaden its expanded access program for its investigational drug, Trappsol® Cyclo™, currently being studied for Niemann Pick Disease Type C (NPC).

“As our clinical trials using intravenous Trappsol® Cyclo™ proceed, we will provide our drug on an expanded use basis to NPC patients in the United States who may not be eligible for our current trials,” said N. Scott Fine, CTD Chairman and CEO. “This may be of help to NPC patients who are unable to receive the drug via formal trials.”

CTD has the only open clinical trials studying cyclodextrins for NPC for patients older than 2 years.

CTD began its compassionate use program in 2009 in the United States when Dr. Caroline Hastings provided its drug on an expanded use basis to Addi and Cassi Hempel. Soon thereafter, physicians around the world used the Hastings-Hempel expanded access protocol to provide the drug to NPC patients, using intravenous (IV), intrathecal (IT) and intracerebroventricular (ICV) routes of administration. Data from those early expanded access programs supported CTD’s formal clinical trial applications for the two ongoing intravenous trials in the United States, United Kingdom, Sweden and Israel (NCT02939547 and NCT02912793). CTD currently provides Trappsol® Cyclo™ via expanded access programs in Brazil and several European countries. With today’s announcement, CTD re-instates the US program in early 2019.

CTD will support intravenous administration of Trappsol® Cyclo™ in the broadening of its expanded access programs. The drug will be made available at no cost in the United States. CTD will collect safety data from all patients participating in expanded access programs, in keeping with regulatory requirements. The additional safety data from the new individual expanded access programs will assist in the design of the pivotal trial for intravenous Trappsol® Cyclo™.

Physicians and other healthcare professionals who would like more information about CTD’s expanded access programs or its clinical trials should contact Dr. Sharon Hrynkow,

Senior Vice President for Medical Affairs, at sharon.hrynkow@cyclodex.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 two ongoing formal clinical trials (Clinical Trials.gov NCT02939547 and NCT02912793). 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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