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CTD Holdings Receives Rare Pediatric Disease Designation for Trappsol(R) Cyclo(TM)

ALACHUA, FL -- (Marketwired) -- 12/06/17 -- 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 it has received rare pediatric disease designation from the FDA for its Trappsol® Cyclo™ drug used in the treatment of Niemann-Pick Disease Type C (NPC). NPC is a rare and fatal genetic disease that impacts the brain, lung, liver, spleen, and other organs.

Rare pediatric disease designation is granted by the FDA to drugs that show promise to treat orphan diseases affecting fewer than 200,000 patients in the U.S. and with more than 50% of those affected age 18 years or younger. The designation is an incentive to companies to develop drugs targeting rare diseases, allowing the recipient to apply for the FDA's [Rare Pediatric Disease Priority Review Voucher \(PRV\) Program](#). Application for a PRV is expected to be made by CTD at the time it submits its New Drug Application (NDA) for Trappsol® Cyclo™ to the FDA. A PRV can be used to accelerate FDA review of future NDAs.

"The incentives provided by the Rare Pediatric Disease designation are significant and include the potential to obtain a valuable Rare Pediatric Disease Priority Review Voucher upon approval," said N. Scott Fine, CTD Chairman and CEO. "We are eager to leverage these benefits and to work closely with the FDA and the NPC patient community as we pursue our goal of developing Trappsol® Cyclo™ to treat this devastating rare disease."

Trappsol® Cyclo™ is CTD's proprietary formulation of hydroxypropyl beta cyclodextrin (HPBCD). HPBCD has been found to increase lifespan and reduce symptoms in NPC animal models by stabilizing cholesterol metabolism, the primary defect in NPC. CTD's use of Trappsol® Cyclo™ in named patient programs globally has shown the drug to be safe and well-tolerated in compassionate use settings. CTD currently supports two clinical trials to evaluate the intravenous administration of Trappsol® Cyclo™ in NPC patients, a phase I in the United States, and a phase I/II in Europe and Israel (See [ClinicalTrials.gov NCT 02939547](#) and [NCT 02912793](#)).

"The Rare Pediatric Disease designation coupled with Orphan Drug status in both the U.S. and EU and Fast Track Designation further strengthens our future clinical trial programs as we work with regulators toward market approval," said Dr. Sharon Hrynkow, 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 diseases with unmet medical need. 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. 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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