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CTD Holdings Files Clinical Trial Application with Italian Drug Agency to Continue Advancing Trappsol(R) Cyclo(TM) Drug Development Program to Treat Niemann-Pick Disease Type C

Application describes clinical plans and protocol

ALACHUA, FL -- (Marketwired) -- 12/21/16 -- CTD Holdings, Inc.(OTCQB: CTDH), a clinical-stage biotechnology company that develops cyclodextrin-based products for the treatment of disease, today announced its filing of a Clinical Trial Application (CTA) with Italy's drug regulator, the Agenzia Italiana del Farmaco (AIFA) to conduct a Phase I/II clinical trial in Italy of the Company's Trappsol® Cyclo™ for the treatment of Niemann-Pick Disease Type C, a rare and fatal disease. The study will be led by Dr. Bruno Bembi, of the Santa Maria della Misericordia Hospital in Udine, Italy. Dr. Bembi has extensive experience in treating rare diseases.

"This is yet another important milestone for our company as we continue to build our international Trappsol® Cyclo™ clinical trial program for the treatment of Niemann-Pick Disease Type C," said N. Scott Fine, Chairman and CEO of CTD. "Our submission in Italy complements the progress we are making in the US, UK and Sweden, where our applications to conduct clinical trials have been accepted."

Niemann-Pick Disease Type C (NPC) is a rare and fatal genetic disease. It impacts primarily children but is increasingly diagnosed in older patients who may live with this disability for many years. NPC is a systemic disease, impacting the brain, liver and other organs through abnormal accumulation of cholesterol in cells. CTD is developing Trappsol® Cyclo™, the Company's proprietary formulation of hydroxypropyl beta cyclodextrin, for the treatment of NPC. The product candidate previously received Orphan Drug designation in both the EU and the US.

The most recent CTA describes CTD's phase I/II clinical plans to administer Trappsol® Cyclo™ intravenously to patients in Italy as young as two years old and into adulthood. The trial is a randomized double blind parallel group study to evaluate the safety and tolerability of three doses of Trappsol® Cyclo™, and effects of Trappsol® Cyclo™ on the body as well as how the body metabolizes the drug. Three doses will be evaluated: 1500 mg/kgBW; 2000 mg/kgBW; and 2500 mg/kgBW. Outcome measures will include markers of cholesterol synthesis and cholesterol degradation, and clinical assessments of swallowing, lung function, cognitive ability, and fine motor skills.

About the Company:
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. 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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