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CTD Holdings Announces Plan to Launch Clinical Trial of Trappsol (R) Cyclo (TM) in Alzheimer's Disease

ALACHUA, FL / ACCESSWIRE / March 14, 2019 /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 has initiated planning for a Phase I clinical trial for treatment of Alzheimer's Disease. The trial will use Trappsol® Cyclo™, the company's proprietary formulation of hydroxypropyl beta cyclodextrin, administered intravenously.

"Alzheimer's Disease is a devastating illness for patients and their families. We expect to launch a Phase I trial using Trappsol® Cyclo™ as a first step on our pathway to market approval of Trappsol® Cyclo™ for an Alzheimer's Disease indication," said N. Scott Fine, CTD's Chairman and CEO. "We are planning to meet with FDA in the near term to discuss our plans."

The Alzheimer's Association reports that more than 5 million Americans are living with Alzheimer's Disease today, and this number could grow to 16 million by 2050. Delaying of the onset of symptoms and slowing of disease progression will save patients and families an enormous toll in human suffering and will have economic benefits to the health care system more broadly.

CTD currently supports a single patient expanded access program using Trappsol® Cyclo™ in late-onset Alzheimer's Disease, the most common form of the disease (ClinicalTrials.gov [NCT03624842](https://clinicaltrials.gov/ct2/show/study/NCT03624842)). The program is a collaboration with Diana Kerwin, M.D. of the Kerwin Research Center, CA.

"There is an urgent need for new approaches and new therapies to treat the symptoms of Alzheimer's Disease and slow its progression. This announcement is a cause for hope," said Dr. Kerwin.

CTD's primary clinical trial programs focus on Niemann-Pick Disease Type C (NPC), a genetic disease that leads to accumulation of cholesterol in the cells of NPC patients. Initial data from a Phase I and a Phase I/II trial show a positive safety profile and suggest that, in these patients, Trappsol® Cyclo™ may stabilize cholesterol synthesis and metabolism (see [CTD press release](#)). Because there are links between NPC and Alzheimer's Disease, CTD plans to study Trappsol® Cyclo™ in Alzheimer's patients.

"Cholesterol and other membrane lipids have been found to play a key role in progression of Alzheimer's Disease and in the formation of amyloid beta plaques, one of the hallmarks of Alzheimer's Disease," said Sharon Hrynkow, Ph.D., CTD's Chief Scientific Officer. "We expect this new clinical trial to afford us the opportunity to understand safety, tolerability and effects of Trappsol® Cyclo™ on key markers of Alzheimer's Disease progression in a small group of patients."

Reference: Yao, J.; Ho, D. et al. JEM: 2012 (209): 2501-2513. Neuroprotection by cyclodextrin in cell and mouse models of Alzheimer disease.

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 (ClinicalTrials.gov [NCT02939547](https://clinicaltrials.gov/ct2/show/study/NCT02939547) and [NCT02912793](https://clinicaltrials.gov/ct2/show/study/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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