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CTD Obtains Right of Reference to Alzheimer's Disease Expanded Access Data

ALACHUA, Fla.--(BUSINESS WIRE)-- 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 the Company had obtained a Right of Reference letter to IND 138423. The IND is for "Expanded Access to Trappsol[®] Cyclo[™] for an Individual Patient with Late-Onset Alzheimer's Disease," with Investigator-Sponsor Diana R. Kerwin MD, President of the Kerwin Research Center.

CTD's proprietary formulation of hydroxypropyl beta cyclodextrin, Trappsol[®] Cyclo[™], is the drug product used in the expanded access protocol. The Right of Reference letter gives CTD access to any and all data from the expanded access protocol to develop and commercialize Trappsol[®] Cyclo[™] for the Alzheimer's Disease indication.

CTD Chairman and CEO N. Scott Fine said, "Our collaboration with the Kerwin Research Center is yielding important data on safety of the drug in a geriatric patient as well as information on how our drug may impact Alzheimer's disease progression. The Right of Reference provides CTD with access to data generated from the expanded access protocol, allowing us to continue to work concretely to identify partners to advance the development of Trappsol[®] Cyclo[™] for the Alzheimer's indication."

As reported recently, the IND annual report on "Expanded Access to Trappsol[®] Cyclo[™] for an Individual Patient with Late-Onset Alzheimer's Disease" was received by FDA in May, according to Dr. Kerwin, allowing CTD to continue to support the program into a second year. Trappsol[®] Cyclo[™] is administered once a month by intravenous injection in this protocol (see ClinicalTrials.gov NCT03624842).

Sharon Hrynkow PhD, CTD's Chief Scientific Officer and Senior Vice President for Medical Affairs said, "Alzheimer's Disease or dementia affects 5 million Americans, and the numbers are growing. We look forward to continuing on our development pathway for Trappsol[®] Cyclo[™] as a therapeutic for this insidious 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 three ongoing formal clinical trials (Clinical Trials.gov [NCT02939547](https://clinicaltrials.gov/ct2/show/study/NCT02939547), [NCT02912793](https://clinicaltrials.gov/ct2/show/study/NCT02912793) and [NCT03893071](https://clinicaltrials.gov/ct2/show/study/NCT03893071)). 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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Investor/Media Contact:

Sitrick and Company

Wendy Tanaka

(415) 369-8447

wtanaka@sitrick.com

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