CTD Announces Partnership with Synteract to support the Extension Protocol for its Phase I Clinical Trial in the United States

ALACHUA, FL – (Globe Newswire) – November 8, 2018 – 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 its newest partner in support of its US clinical program, Synteract. Synteract is a full-service Clinical Research Organization which has an existing relationship with CTD in support of its Phase I/II clinical trial at sites in Israel and Sweden. Synteract will support CTD's Extension Protocol, "An Open-Label Extension Study of the Long-Term Safety and Efficacy of Intravenous Trappsol[®] Cyclo[™] (HPBCD) in Patients with Niemann-Pick Disease Type C (NPC-1)," in the United States.

"Synteract is a world-class company with broad expertise in the management and conduct of clinical trials," said N. Scott Fine, CTD's Chairman and CEO. "Their skills will bolster our ability to continue to provide Trappsol[®] Cyclo[™] to individuals suffering from NPC after they complete our US Phase 1 trial. We are deeply committed to the NPC families and the NPC community."

CTD's Extension Protocol for the Phase I trial was approved by FDA in April 2018. The Protocol allows for eligible subjects who have completed the Phase I trial in the US to continue to receive intravenous administration of CTD's Trappsol[®] Cyclo[™], the company's proprietary formulation of hydroxypropyl beta cyclodextrin, until market registration. Participants will be permitted to receive intravenous dosing in the home setting or in the hospital setting. The two clinical sites now participating the Phase I trial are also expected to participate in the Extension Protocol: UCSF Children's Hospital Oakland, led by Caroline Hastings, MD, and Morristown Medical Center of the Atlantic Health System, led by Darius Adams, MD.

"Synteract is now a critical part of CTD's overall clinical program in the United States," said Sharon H. Hrynkow, PhD, CTD's Senior Vice President for Medical Affairs. "As we continue to advance our formal clinical trials, the information gathered via this extension protocol will be useful to the FDA and to regulatory authorities in Europe and Israel as we seek market registration for Trappsol[®] Cyclo[™]."

More information on CTD's Phase I trial is available in a video recording of a webinar held October 16, 2018 and available at <u>www.ctd-holdings.com</u>. On October 3, 2018 CTD published a press release, <u>HERE</u>, outlining top-line data from both of its intravenous Trappsol[®] Cyclo[™] clinical trials now underway in the US, United Kingdom, Sweden and Israel.

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

About Synteract:

Synteract is an innovative, full-service CRO, with employees across 21 countries, supporting biotech and pharma companies across all phases of drug development to help bring new medicines to market. Synteract offers a notable depth of therapeutic expertise in oncology, dermatology, and neuro degenerative indications, as well as rare and orphan and pediatrics. For more information visit: <u>www.synteract.com</u>

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.

Investor/Media Contact:

Sitrick and Company

Wendy Tanaka (415) 369-8447 wtanaka@sitrick.com

Thomas Mulligan (212) 573-6100, Ext. 395 tmulligan@sitrick.com