



CTD Holdings Announces Approval of Clinical Trial Application to Conduct Phase I/II Clinical Study of Trappsol(R) Cyclo(TM) in Patients with Niemann-Pick Type C Disease in Israel

Two New Israeli Sites Now Recruiting Patients in Multicenter European Trial

ALACHUA, FL – (Marketwired) – September 18, 2017 – CTD Holdings, Inc. (OTCQB: CTDH), a clinical stage biotechnology company developing cyclodextrin-based products for the treatment of diseases with unmet medical need, today announced that the Israeli Ministry of Health (MOH) has approved CTD Holdings' Clinical Trial Application to conduct its ongoing Phase I/II clinical study in patients with Niemann-Pick Disease Type C (NPC) at two sites in Israel: the Soroka University Medical Center in Beer Sheva and Emek Medical Center in Afula. NPC is a rare and fatal genetic disease affecting the liver, spleen, lungs, brain and other organs. The study, which has already enrolled in Europe, is evaluating CTD's proprietary hydroxypropyl beta cyclodextrin, Trappsol(R) Cyclo(TM), for safety and efficacy in NPC patients. The Israeli MOH approval represents the fourth regulatory body outside of the U.S. to approve the study, joining the UK, Sweden and Italy.

"There is a strong tradition of Israeli cooperation in clinical trials ultimately reviewed at the central European level. We are pleased and excited to include Israel in this Phase I/II clinical study and in our work toward market registration of Trappsol(R) Cyclo(TM) in the EU," said N. Scott Fine, CTD Holdings' Chairman and CEO.

The addition of the Soroka University Medical Center and Emek Medical Center brings the total number of sites involved in the Phase I/II study to six. The company expects patients to be enrolled at both Israeli sites by the end of October 2017.

"Addition of these sites will allow us to rapidly expand our enrollment, especially among pediatric patients," said Dr. Sharon Hrynkow, CTD's Senior Vice President for Medical Affairs and lead for the company's clinical program.

NPC is characterized by accumulation of cholesterol in the lysosomal compartment of every cell in the body. It may present in infants and young children, as well as in adolescents and into adulthood.

"This is a devastating diagnosis for parents to receive since all patients will ultimately succumb to the disease in one way or another," said Dr. Orna Staretz-Chacham, neonatologist and lead investigator for the study at Soroka University Medical Center. "And, since NPC is a systemic disease, it presents differently in each patient, often leading to under-diagnosis or misdiagnosis of the disease. Our great hope is that this study will lead to an approved drug that will be an effective systemic treatment for NPC."

To date, intravenous Trappsol(R) Cyclo(TM) has been administered to 21 NPC patients worldwide, some for more than six years, via Compassionate Use Programs. Data from treating physicians in the Compassionate Use Programs have demonstrated that multiple patients have shown marked improvements in neurological symptoms, lung function or liver morphology, or had stabilization of disease progression, with no significant safety concerns.

The incidence of NPC in Israel is higher in some sub-populations than in the general population due to marriage patterns and cultural norms. Dr. Ronen Spiegel, a clinical geneticist and chairman of pediatrics at Emek Medical Center, also the lead investigator for the study at Emek Medical Center said, "We are excited to be able to join this study and to contribute to the knowledge base that will ultimately help not only our patients in Israel, but NPC patients everywhere."

In addition to the Phase I/II clinical study based in Europe and Israel, the Company is also conducting a Phase I clinical study in the United States. CTD Holdings previously received Orphan Drug designation for the use of Trappsol(R) Cyclo(TM) in NPC from the U.S. Food and Drug Administration and the European Medicines Agency and Fast Track designation for the Phase I study in the United States.

About the clinical trials:

For families interested in learning more about CTD's EU trial or the US trial, please contact CTD's Patient Liaisons:

- Ms. Jackie Imrie, based in the UK, at jackie@jicltd.co.uk
- Ms. Shannon Reedy, based in the U.S., at Shannon.Reedy@hotmail.com
- Dr. Caroline Hastings, Principal Investigator for the US trial and Senior Clinical Advisor to the EU study, at chastings@mail.cho.org or 510-428-3631 (office).

Physicians in Israel may contact:

- Dr. Orna Staretz-Chacham at staretz@bgu.ac.il, or
- Dr. Ronen Spiegel at spiegelr@zahav.net.il or 972-505927697 (mobile);

For physicians interested in learning more about the EU trial or the US trial, please contact:

- Dr. Hastings (see contact information above), or
- Dr. Reena Sharma, Coordinating PI for the EU trial, at reena.sharma@srft.nhs.uk, or
- Dr. Sharon Hrynkow, at sharon.hrynkow@cyclodex.com.

For additional information, please visit:

- Phase I: <https://clinicaltrials.gov/ct2/show/NCT02939547>
- Phase I/II: <https://clinicaltrials.gov/ct2/show/NCT02912793>

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(R) Cyclo(TM), 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(R) Cyclo(TM) 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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