

July 19, 2017



CTD Holdings Announces First Patient Dosed in Phase I/II Clinical Trial to Evaluate Trappsol(R) Cyclo(TM) in Niemann-Pick Disease Type C

Study Evaluating Safety and Efficacy of Trappsol(R) Cyclo(TM) in a Multi-center European Trial

Company Expects Final Data from Trial by End of 2018

ALACHUA, FL -- (Marketwired) -- 07/19/17 -- CTD Holdings, Inc. (OTCQB: CTDH), a clinical stage biotechnology company developing cyclodextrin-based products for the treatment of disease, today announced that the first patient has been dosed intravenously in the Company's European Phase I/II clinical trial evaluating Trappsol® Cyclo™ in patients with Niemann-Pick Disease Type C (NPC), a rare and fatal genetic disease that impacts the brain, lung, liver, spleen, and other organs.

The first patient was dosed by Dr. Reena Sharma and her team at Salford Royal NHS Foundation Trust in the United Kingdom. Dr. Sharma is Consultant for Adult Metabolic Medicine and Honorary Senior Lecturer at the Mark Holland Metabolic Unit of the Salford NHS Trust, and the Coordinating Investigator for the Phase I/II trial of Trappsol® Cyclo™ in Europe. The first patient visit was supported by NIHR Manchester Clinical Research Facility, which provides 24-hour cover for intensive and complex research studies.

"There is currently no treatment available globally for this condition. Those that are available, are limited to delaying the progression of neurological symptoms or providing palliative care to relieve, for example, the gastrointestinal symptoms and seizures," said Dr. Sharma. "We need new treatments that help to address progression of neurological involvement and some of the other problems our patients experience relating to the liver, spleen and lungs. I hope that this study will lead to a new treatment for this devastating condition."

The Phase I/II clinical trial, which will include additional sites in the UK and Sweden and is also expected to be expanded to Italy, requires 12 patients to be fully enrolled. The trial will evaluate the safety and efficacy of Trappsol® Cyclo™ in NPC patients ages two and older. Patients will be randomized into three dose groups of 1500 mg/kg, 2000 mg/kg and 2500 mg/kg of Trappsol® Cyclo™ administered via bi-weekly intravenous injections over a period of 48 weeks.

"Commencement of dosing of the first patient at the Salford clinical site is another significant milestone for the Company in the development of our Trappsol® Cyclo™," said CTD Chairman and CEO, N. Scott Fine. "We expect final data from this important clinical trial by the end of 2018. CTD remains grateful for the continued support from the many patient families, researchers and clinicians, such as Dr. Sharma, who have helped us reach this important milestone."

Trappsol® Cyclo™ is a parenteral grade of hydroxypropyl beta cyclodextrin, a donut-shaped molecule comprised of seven glucopyranose units. To date, intravenous Trappsol® Cyclo™ 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 program 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.

In addition to the European study, CTD Holdings has initiated a Phase I clinical trial in the U.S. evaluating intravenous administration of Trappsol® Cyclo™ in NPC patients. CTD previously received Fast Track Designation in the U.S. and Orphan Drug Designation for the use of Trappsol® Cyclo™ in the treatment of NPC from the U.S. Food and Drug Administration and the European Medicines Agency.

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@jicld.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 / Phone 510-428-3631

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

- Dr. Sharon Hrynkow, CTD's Senior Vice President for Medical Affairs at sharon.hrynkow@cyclodex.com, or
- Dr. Hastings (see contact information above), or
- Dr. Sharma at reena.sharma@srft.nhs.uk .

For additional information, please visit:

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

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

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. 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.

Investor/Media Contact:

Hans Vitzthum
LifeSci Advisors, LLC
212-915-2568
Hans@lifesciadvisors.com

Source: CTD Holdings, Inc.