August 23, 2018

CTD Holdings' Trappsol® Cyclo™ Featured in Television Program on Niemann-Pick Disease Type C

ALACHUA, Fla., Aug. 23, 2018 (GLOBE NEWSWIRE) -- CTD Holdings, Inc. (OTCQB: CTDH), a clinical stage biotechnology company that develops cyclodextrin-based products for the treatment of disease with unmet medical need, commented on a recent television program featuring Trappsol (R) Cyclo(TM).

On August 19 and August 20, 2018, CNN's HLN channel aired an episode, "What's Wrong with the Twins?" as part of the series "Something's Killing Me." The episode told the story of Chris and Hugh Hempel and their identical twin girls, Addi and Cassi, who have Niemann-Pick Disease Type C (NPC), a rare and fatal genetic disease. When the Hempels learned of the NPC diagnosis, they searched for experimental treatments that could stall or cure the disease, which results from cholesterol accumulation in every cell in the body. Their search led them to a Trappsol(R) brand cyclodextrin, hydroxypropyl beta cyclodextrin (HPBCD), and to CTD Holdings.

Trappsol(R) brand HPBCD is a ring of seven glucopyranose sugars with hydroxypropyl groups attached that has a particular affinity for cholesterol. It was given to the twins on an "expanded access" basis starting in 2009. Expanded access programs allow physicians to request from FDA the use of unapproved drugs in situations where no treatments exist for deadly diseases. Dr. Caroline Hastings, the Hempel's physician, worked with CTD, the family, and a team of experts for over a year to gain FDA approval of a protocol to administer Trappsol(R) brand HPBCD to the twins. In 2009, the Hempel girls began intravenous use of Trappsol(R) brand HPBCD. A year later, wishing to determine if more material could be delivered to the brain via an intrathecal route (through the cerebrospinal fluid), again FDA approved a protocol to allow Dr. Hastings to proceed. Around this time the specific Trappsol(R) brand HPBCD used was rebranded as Trappsol(R) Cyclo(TM) and this is the product used in all subsequent clinical activities.

Over the following years, and with the sharing of the protocol to administer the product on the internet, many more NPC families followed in Dr. Hastings' steps. Today, Dr. Hastings is the Principal Investigator of CTD's Phase I clinical trial to administer Trappsol(R) Cyclo(TM) intravenously to NPC patients, and she is the Senior Clinical Advisor to CTD's Phase I/II clinical trial using Trappsol(R) Cyclo(TM) intravenously in NPC patients, which is now underway in the United Kingdom, Sweden and Israel. Dr. Hastings still treats NPC patients through expanded access programs and is a practicing Pediatric Hematologist/Oncologist and Director of Fellowships at UCSF Benioff Children's Hospital Oakland.

N. Scott Fine, Chairman and CEO of CTD Holdings, said, “We are honored to have been the first company to provide HPBCDs in the form of Trappsol(R) to the Hempel family, and then to families worldwide through expanded access programs. Today, as we work toward market registration of Trappsol(R) Cyclo(TM) for NPC patients, we are building on the work begun so bravely by Chris and Hugh Hempel, and Addi and Cassi.”

Dr. Caroline Hastings said, “Today, the Hempel twins are 14 years old and they enjoy quality time with their family. Knowing the trajectory of the disease, it is highly unlikely that the girls would be with us today were it not for expanded access use of Trappsol(R) Cyclo(TM).”

The program also featured prominently Dr. Benny Liu who, in 2007, was a researcher at the University of Texas Southwestern Medical Center and who made the groundbreaking discovery that HPBCDs could overcome NPC defects in a mouse model of the disease. NPC mice that received HPBCDs lived longer and had a delay in onset of symptoms. Importantly, their cholesterol levels were markedly reduced. Dr. Liu is Co-Principal Investigator with Dr. Hastings on CTD’s phase I clinical trial using Trappsol(R) Cyclo(TM) intravenously to treat NPC. Both Dr. Liu and Dr. Hastings serve on CTD’s Scientific Advisory Board. Dr. Liu is a practicing Gastroenterologist at Alameda Health System, Oakland, California.

Dr. Liu recounts in the program his reaction when Chris Hempel phoned him to ask about using Trappsol(R) HPBCD in the twins. “We all thought it was a little crazy since the drug was not approved, but Chris Hempel is a force of nature. No one could turn her down,” said Dr. Liu. His advice was for her to call CTD, and the first shipment of Trappsol(R) HPBCD was sent soon thereafter.

At the end of the show, the host speculates about other possible uses for “cyclodextrin” since cholesterol is a risk factor for many diseases. Earlier this year, CTD entered into a partnership to provide Trappsol(R) Cyclo(TM) intravenously and on an expanded access basis to a patient with Alzheimer’s Disease, one of the many diseases for which cholesterol is a risk factor.

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(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, 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(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.

Investor/Media Contact:
Sitrick and Company

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

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

Source: CTD Holdings, Inc.