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Cyclo Therapeutics Signs Agreement with Worldwide Clinical Trials to Conduct Alzheimer's Disease Clinical Trial

Trial Will Evaluate Safety and Efficacy of the Company's Trappsol® Cyclo™ Drug in Alzheimer's Disease

GAINESVILLE, Fla.--(BUSINESS WIRE)-- Cyclo Therapeutics, Inc. (OTCQB: CTDH), a clinical-stage biotechnology company that develops cyclodextrin-based products for the treatment of Niemann-Pick Disease Type C and Alzheimer's Disease, today announced that it has signed an agreement with Worldwide Clinical Trials (Worldwide), a leading Contract Research Organization (CRO), to conduct a clinical trial to evaluate safety and efficacy in Alzheimer's Disease. The trial will evaluate Trappsol® Cyclo™ given by intravenous infusion. The Company has previously reported encouraging data on safety and efficacy of the product based on an FDA-approved expanded access program in a single patient with late-onset Alzheimer's Disease.

Alzheimer's Disease affects 5.7 million Americans. While a few symptomatic treatments are available, there are no approved disease modifying treatments.

"We are very excited to work with Worldwide, an industry leader, on this critical clinical program," said N. Scott Fine, Company Chairman and CEO. "Our work to advance an innovative approach to treat this devastating disease may lead to improvements in the lives of Alzheimer's patients and their families. We are pleased to have Worldwide's team of experts working closely with us as we begin our development pathway."

"The scientific, medical and operational experts at Worldwide offer nearly 40 years of hard-won insight gleaned from our experience on the front lines of Alzheimer's Disease research. The journey toward halting progression of this devastating neurodegenerative disorder takes tenacity, and we're not about to give up now," said Henry Riordan, executive vice president, Scientific Solutions, for Worldwide. "We are thrilled to be selected by the innovators at Cyclo Therapeutics as their partner in the development of this exciting new treatment approach."

Cyclo Therapeutics and Worldwide are designing the trial protocol and expect to schedule a scientific advice meeting with the U.S. FDA in early 2020. Patient enrollment is expected to begin shortly thereafter.

About Cyclo Therapeutics:

Cyclo Therapeutics, 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 in three ongoing formal clinical trials for Niemann-Pick Disease Type C, a rare and fatal genetic disease, (Clinical Trials.gov NCT02939547, NCT02912793 and NCT03893071) and in an Expanded Access program for late-onset Alzheimer's Disease (NCT03624842). Additional indications for the active ingredient in Trappsol® Cyclo™ are in development. For additional information, visit the company's website: www.cyclotherapeutics.com

About Worldwide Clinical Trials:

Worldwide Clinical Trials employs more than 1,700 professionals around the world, with offices in North and South America, Eastern and Western Europe, Russia, and Asia. Founded by physicians committed to advancing medical science, Worldwide is out to change how the world experiences CROs – in the best possible way. From early phase and bioanalytical sciences through late phase, post-approval and real-world evidence, we provide world-class, full-service drug development services.

With infrastructure and talent spanning 60 countries, we execute predictable, successful studies with operational excellence across a range of therapeutic areas, including central nervous system, cardiovascular, metabolic, general medicine, oncology and rare diseases. We never compromise on science or safety. We're never satisfied with the status quo. We're the Cure for the Common CRO.

For more information, visit http://www.worldwide.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:
RedChip Companies, Inc.
Victor Roberts

407-571-0909
victor@redchip.com

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