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Cyclo Therapeutics' Chief Scientific Officer Appointed to President's Council of Advisors on Science and Technology

ORLANDO, Fla / ACCESSWIRE / December 10, 2019 /Sharon H. Hrynkow, Ph.D., Chief Scientific Officer of Cyclo Therapeutics (OTCQB: CTDH), was appointed to the President's Council of Advisors on Science and Technology (PCAST) in October.

Dr. Hrynkow, a neuroscientist by training, has served in executive leadership roles at the National Institutes of Health, as the inaugural President of the Global Virus Network, a non-profit organization, and as Senior Science Advisor at the Department of State.

Currently, Dr. Hrynkow leads CTDH's clinical and scientific programs developing the company's drug, Trappsol® Cyclo™, for treatment of Niemann-Pick Disease Type C (NPC), a rare and fatal disease in children, and for Alzheimer's Disease (AD). She also Co-Chairs the company's Scientific Advisory Board.

"Advances in science and technology are major drivers of US economic growth, and they contribute to our nation's security," said Dr. Hrynkow. "I am delighted to serve on PCAST to work with colleagues across many disciplines to find solutions to critical science and technology challenges facing our nation."

PCAST was launched by Executive Order in 2001, formalizing a process that had been in place through many previous Administrations to advise the President on matters involving science, technology, education, and innovation policy.

The Council includes distinguished individuals from sectors outside of the Federal Government and represents diverse perspectives and expertise in science, technology, education and innovation.

The announcement of the re-chartering of PCAST ends a period of more than 33 months since President Barack Obama's council held its final meeting in January 2017.

Dr. Hrynkow is one of the first seven members appointed to PCAST by President Trump. The council will ultimately have 16 members.

Positive Results in NPC and AD Development Programs

As Chief Scientific Officer and Senior Vice President for Medical Affairs at CTDH, Dr. Hrynkow has played a vital role in leading the company's clinical and scientific program since joining the company in 2015.

Some of that success can be seen in CTDH's recent publication of the most extensive set of case studies to-date on expanded access use (or "compassionate use") of hydroxypropyl betacyclodextrin to treat patients with NPC.

The manuscript was published on October 21, 2019 in the Orphanet Journal of Rare Diseases, a scientific, peer-reviewed publication (see <https://www.ncbi.nlm.nih.gov/pubmed/31639011>).

Eighty percent of the patient use data presented in the manuscript derives from CTDH's Trappsol® Cyclo™ product, the company's proprietary formulation of hydroxypropyl betacyclodextrin.

In an extensive review of the data, hydroxypropyl betacyclodextrin was found to be safe when administered intravenously, and individual patients showed improvements in disease symptoms.

Other highlights of the manuscript are that physicians noted that their patients receiving intravenous cyclodextrin showed improvements in ability to walk and to write, increased alertness, improved ability to communicate, and enhanced overall well-being.

As well, individual treated patients exhibited reduction in hepatic volume and improvement in liver transaminases, restoration of language skills, and resolution of interstitial lung disease.

Similar positive early findings have been reported by CTDH in its work in AD.

CTDH has been intravenously administering its proprietary Trappsol® Cyclo™ product to an Alzheimer's patient for more than a year under an FDA compassionate use program.

In a required annual report to the FDA filed in May 2019, the company reported data that suggest a positive safety profile for the drug in the Alzheimer's patient, overall stabilization of disease, and improvement in certain behavioral aspects of the disease. Given that persons with AD dementia are generally expected to decline during a one-year timeframe, the results with this patient are extremely promising.

"The report suggests cognitive and neurologic stability, indicating possible benefit," said Dr. Hrynkow.

The expanded access program has been funded externally, with CTDH providing key materials, expertise, and support, in addition to the drug itself.

Alzheimer's Is Currently the Most Common Form of Dementia

According to the Alzheimer's Association, 5.8 million Americans are living with Alzheimer's Disease. By 2050, this number is projected to rise to nearly 14 million.

It's estimated that Alzheimer's and other dementias cost the US \$290 billion annually. These costs could rise as high as \$1.1 trillion by 2050.

Despite its prevalence, after more than 30 years of research, there is still no cure for Alzheimer's, and only a handful of medications have reached the market.

Leading CRO to Conduct Alzheimer's Clinical Trial

In November, CTDH signed an agreement with Worldwide Clinical Trials, a leading Contract Research Organization (CRO), to conduct a clinical trial to evaluate the safety and efficacy of the company's Trappsol® Cyclo™ in AD.

Worldwide is an award-winning company that has been recognized by organizations from around the world for its outstanding services and expertise, receiving numerous awards and rankings by respected industry associations and awards programs, including Informa's Scrip Awards, Life Science Leader's CRO Leadership Awards, and Nice Insight, the research division of That's Nice, A Science Agency.

Founded by physicians dedicated to advancing medical science and built on an unwavering commitment to operational excellence, Worldwide is able to strategically balance science, medicine, operations, and commercial intelligence to achieve successful drug development.

Worldwide employs more than 1,700 professionals around the world, with offices in North and South America, Eastern and Western Europe, Russia, and Asia.

From early phase and bioanalytical sciences through late phase, post-approval and real-world evidence, Worldwide provides world-class, full-service drug development services.

"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."

CTDH 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.

Phase I/II Trials Underway in NPC

Niemann-Pick Disease Type C (NPC) is a rare and fatal genetic disease affecting 1 in 100,000 live births globally.

NPC affects every cell in the body due to the defect in the NPC protein which is responsible for cholesterol processing in the cell. Because of the NPC protein defect, cholesterol accumulates abnormally in every cell in the body, causing symptoms in the brain, liver, spleen, lungs, and other organs. There are no approved drug therapies for NPC in the United States, and only one, Miglustat/Zavesca, in Europe.

Trappsol® Cyclo™, the same drug used in CTDH's Alzheimer's patient expanded access program, is already in Phase I/II trials for NPC. A Phase I trial in the US has completed enrollment, with top-line results expected in early 2020.

In 2019, CTDH presented initial findings from the Phase I and Phase I/II trials at multiple medical conferences, showing promising results for drug safety and efficacy in NPC. Specifically, Trappsol® Cyclo™ clears cholesterol from cells as shown by blood biomarkers

of cholesterol synthesis and metabolism and by liver histology. Initial results from the Phase I/II trial show benefit of the drug on neurologic features of the disease, consistent with earlier findings from compassionate use programs.

Trappsol® Cyclo™ has been granted Orphan Drug Designation (ODD) by the FDA and European Medicines Agency, as well as both Rare Pediatric Disease and Fast Track designations in the US. ODD gives CTDH market exclusivity for 7 and 12 years in the US and EU, respectively.

Frazier, Browne and Mayer's *Strategic Allocator*, a monthly research and advisory journal for RIAs and high net-worth individuals, gave CTDH a buy rating in September, citing the company's upcoming Phase III trial in NPC, which will also be conducted in partnership with Worldwide, and the potential from the company's Alzheimer's program.

CTDH is the first OTC stock *Strategic Allocator* has recommended its readers buy, according to publisher David Frazier.

Second Buy Recommendation from *Breakthrough Technology Alert's* Ray Blanco

Ray Blanco, editor of [*Technology Profits Confidential*](#) as well as [*Breakthrough Technology Alert*](#), [*Ray Blanco's FDA Trader*](#), [*Penny Pot Profits*](#), [*Ray Blanco's Pot Stock Mastermind*](#), and [*Technology Profits Daily*](#), issued a buy recommendation on CTDH in November, citing the company's several hundred-million-dollar per year opportunity in Niemann Pick Type C (NPC) disease and the even larger, multi-billion-dollar per year opportunity in Alzheimer's disease.

"I believe a good deal of clinical risk has been removed from the equation, with patients having measurably benefited from this compound since 2009," commented Blanco. "Orphan drugs often command prices in the range of \$200,000-\$500,000 per patient per year. Big pharmaceutical franchises have been built exclusively to find therapies for orphan indications. In NPC, Cyclo Therapeutics has a market opportunity worth several hundred million dollars per year with Trappsol® Cyclo™ having received FDA Orphan Drug designation."

Board Members Invest \$10M+ into CTDH

Board members at CTDH, including multiple outside directors, have invested more than \$10 million into the company in recent years, including more than half a million shares purchased since May of this year alone.

Board member Markus Sieger, President and CEO of Polpharma Group, purchased 100,000 shares in August, increasing his total position to more than 4.5 million shares. Polpharma is among the top 20 generic drug manufacturers in the world. Its portfolio includes about 600 products and another 200 in development.

Patrick Ostronic, an officer of US Pharmacia International and CFO of its parent company, The USP Group, personally purchased 350,000 shares of CTDH in the weeks following the company announcing its plans to launch an Alzheimer's trial. As of the latest filing, Ostronic himself owned more than 1.3 million shares of CTDH. USP has been a trend setter in the OTC medicine market for over 20 years and is currently the leading company in the OTC

sector of the Polish pharmaceutical market, employing around 700 people across Eastern Europe and the United States with a portfolio of more than 100 products.

Former President & COO of Colgate-Palmolive Owns 2.5M+ Shares

Also serving on CTDH's board is William Shanahan, the retired President and COO of Colgate-Palmolive. Shanahan joined CTDH's board in 2016 and now owns more than 2.6 million shares of CTDH as of the latest filings, which include his 800,000-share purchase in May 2019 and his purchase of 415,000 shares in August and September 2019.

Low Valuation Relative to Potential Upside

With a \$500M+ annual addressable market in NPC and a \$1B+ annual addressable market in AD, CTDH offers a compelling opportunity for potential upside from its current valuation, and with an institutional round of \$7.4 million in equity financing closed in 2019, CTDH has a strong balance sheet to move its programs forward.

Despite these and many other strengths, the company's stock trades for a market cap of less than \$30 million. As the company continues to achieve major milestones and more investors learn of the opportunity, shares could begin moving toward a more realistic and higher valuation.

Learn more about CTDH, its work in Alzheimer's, and its clinical trials for NPC, by visiting CTDHinfo.com, where you can sign up for free news alerts to stay abreast of the latest developments of this exciting opportunity.

Additional information is available at the company's [website](#) and in their latest [investor presentation](#).

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