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Cyclo Therapeutics Receives Buy Recommendation and $1.25 Price Target from ThinkEquity

ORLANDO, FL / ACCESSWIRE / December 18, 2019 /Cyclo Therapeutics, Inc. (OTCQB:CTDH), a clinical-stage biotechnology company that develops cyclodextrin-based products for the treatment of disease, received a buy recommendation and $1.25 price target from ThinkEquity, a division of Fordham Financial Management.

ThinkEquity's research report on Cyclo Therapeutics focused primarily on the company's development of a treatment for Niemann-Pick Disease Type C (NPC), a rare and fatal genetic disease.

Assuming continued positive results from clinical trials underway, the report forecasts Cyclo Therapeutics will receive FDA approval and begin generating revenue from its NPC treatment in 2022, with estimates of a potential $75 million in annual sales in the US.

While the ThinkEquity analyst notes the company's recently announced development program for Alzheimer's Disease (AD), it stops short of including any potential upside from the program in its current price target forecast.

As additional milestones are achieved in the AD program, the price target could be revised significantly higher.

Positive Results in NPC and AD Development Programs

Cyclo Therapeutics recently published the most extensive set of case studies to-date on expanded access use (or "compassionate use") of hydroxypropyl beta cyclodextrin 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 Cyclo Therapeutics' Trappsol® Cyclo™ product, the company's proprietary formulation of hydroxypropyl beta cyclodextrin.

In an extensive review of the data, hydroxypropyl beta cyclodextrin 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 Cyclo Therapeutics in its work in AD.

Cyclo Therapeutics has been intravenously administering its proprietary Trappsol® Cyclo™ product to a late-onset 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 late-onset 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. Sharon Hrynkow, Cyclo Therapeutics' Chief Scientific Officer.

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

Phase I/II Trials Underway in NPC

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 Cyclo Therapeutics' Alzheimer's patient compassionate use 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, Cyclo Therapeutics 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 Cyclo Therapeutics market exclusivity for 7 and 12 years in the US and EU, respectively.

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, Cyclo Therapeutics 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 and scientists dedicated to advancing medical science and build 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, PhD, executive vice president, Scientific Solutions, and Co-Founder of 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.

Board Members Invest $10M+ into Cyclo Therapeutics

Board members at Cyclo Therapeutics, 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 Cyclo Therapeutics 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 Cyclo Therapeutics. 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 Cyclo Therapeutics' board is William Shanahan, the retired President and COO of Colgate-Palmolive. Shanahan joined Cyclo Therapeutics' board in 2016 and now owns more than 2.6 million shares of Cyclo Therapeutics 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, Cyclo Therapeutics 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, Cyclo Therapeutics 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 Cyclo Therapeutics, 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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