PRESS DETAILS

Clene Nanomedicine Receives Catalyst Award for Healthy Longevity from U.S. National Academy of Medicine to Accelerate the Development of CNM-Au8 for Neurodegenerative Diseases Associated with Aging

May 17, 2021

International award will fund preclinical study of CNM-Au8 nanocatalysis for the improvement of human health and lifespan in the contexts of aging and Alzheimer's disease

Clene anticipates the expansion of disease indications for CNM-Au8 beyond amyotrophic lateral sclerosis, Parkinson's disease, and multiple sclerosis

SALT LAKE CITY, May 17, 2021 (GLOBE NEWSWIRE) -- Clene Inc. (NASDAQ: CLNN) (along with its subsidiaries, "Clene") today announced that its wholly owned subsidiary Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company dedicated to the treatment of neurodegenerative disease using bioenergetic nanocatalysis, received a Healthy Longevity Catalyst Award from the U.S. National Academy of Medicine (NAM) to accelerate the preclinical development of CNM-Au8, a bioenergetic nanocatalyst, for treatment of neuronal aging-related deficits and Alzheimer's disease. The Healthy Longevity Global Competition was founded in 2019 by NAM to 'kickstart innovation by the world's greatest minds' to support worldwide healthy longevity.

NAM and its seven global collaborators received over 1500 applications and ultimately issued more than $7.7 million in prizes in the inaugural round of Catalyst Awards, part of the broader Healthy Longevity Global Competition. Clene was awarded a NAM Catalyst Award based on the novelty and innovation of CNM-Au8 as a therapeutic approach to neuronal aging-related diseases. In addition to receiving a prize, awardees will participate in the first annual Healthy Longevity Innovator Summit in September 2021 to share their work with policy makers, researchers, and fellow innovators from around the world.

"We are delighted to have received this award from the U.S. National Academy of Medicine in recognition of the potential of our therapeutic nanocatalyst, CNM-Au8, to contribute to healthy longevity," said Rob Etherington, President and Chief Executive Officer. "At Clene, we are dedicated to revolutionizing the treatment of neurodegenerative disease using bioenergetic nanocatalysts. The support from NAM provides an opportunity to potentially expand CNM-Au8's target indications to additional neurodegenerative diseases of aging, including Alzheimer's disease. CNM-Au8 is currently being investigated in four Phase 2 and one Phase 3 clinical trial for the treatment of amyotrophic lateral sclerosis, Parkinson's disease, and multiple sclerosis."

The NAM funding supports a collaborative preclinical effort demonstrating the unique bioenergetic effects of CNM-Au8 on deficits associated with aging and Alzheimer's disease. The study will be led by Dr. Karen Ho, Head of Translational Medicine at Clene, in collaboration with Assistant Professor Jerome Mertens of the University of Innsbruck (Austria), whose expertise lies in reprogramming human cells into directly induced neurons that retain epigenetic and metabolic markers of aging. The work aims to identify key mechanisms by which CNM-Au8 may impact age-related neurodegenerative diseases, including Alzheimer's disease.

Professor Mertens of the Neural Aging Laboratory, Institute for Molecular Biology, University of Innsbruck, Austria, commented, "I am very excited about this project with Clene, and am grateful for the support coming from the National Academy of Medicine. Finding strategies to interfere with age-dependent neurodegeneration is a difficult process, but we are very optimistic that a great deal of information will be learned by testing CNM-Au8 in the context of its actual target cells, which are older human neurons."

About Alzheimer's Disease
Alzheimer's disease is the most common type of dementia, with an estimated 5.8 million Americans living with Alzheimer's disease in 2020. It is a progressive neurodegenerative disease affecting memory, cognition, and language. Age is the best-known risk factor for the disease. There is currently no known treatment that can stop or halt the progression of this disease.

About CNM-Au8

Clene's lead drug candidate, CNM-Au8, a bioenergetic nanocatalyst, is a stable, aqueous suspension of catalytically active gold (Au) nanocrystals. Resulting from a patented manufacturing breakthrough, the self-organized, clean surfaced nanocrystals of CNM-Au8 drive critical cellular bioenergetic reactions in the brain that increase cellular energy, enhance neurorepair, and improve neuroprotection. CNM-Au8 crosses the blood-brain barrier and is not associated with the toxicities related to synthetic gold compounds or nanoparticles manufactured via alternative methods. CNM-Au8 is currently being evaluated in a Phase 3 registration trial in amyotrophic lateral sclerosis (ALS), a Phase 2 trial examining disease progression via a novel electromyography technique in patients with early ALS, a Phase 2 trial for the treatment of chronic optic neuropathy in patients with stable relapsing multiple sclerosis (MS), and Phase 2 brain target engagement studies in patients with Parkinson's disease (PD) and MS. CNM-Au8 has demonstrated safety in Phase 1 studies in healthy volunteers and has shown both remyelination and neuroprotective effects in multiple preclinical (animal) models. Preclinical data, both published in peer-reviewed journals and presented at scientific congresses, demonstrate that treatment of neuronal cultures with CNM-Au8 improves survival of neurons, protects neurite networks, decreases intracellular levels of reactive oxygen species and improves mitochondrial capacity in response to cellular stresses induced by numerous disease-relevant neurotoxins. Oral treatment with CNM-Au8 improved functional behaviors in rodent models of ALS, MS, and PD versus vehicle (placebo).

About Clene

Clene, a clinical-stage biopharmaceutical company focused on neurodegenerative disease, is leading the way by using nanotechnology to treat bioenergetic failure, which underlies many neurological diseases. Clene has innovated a novel nanotherapeutic platform to create a new class of drugs—bioenergetic nanocatalysts. Clene's lead drug candidate, CNM-Au8, is a concentrated nanocrystalline gold (Au) suspension that drives critical cellular bioenergetic reactions in the CNS. CNM-Au8 increases cellular energy to accelerate neurorepair and improve neuroprotection. Currently, CNM-Au8 is being investigated for efficacy and safety in a Phase 3 registration trial for ALS and in Phase 2 trials for multiple sclerosis and Parkinson's disease. Clene has also advanced into the clinic an aqueous solution of ionic zinc and silver for anti-viral and anti-microbial uses. The company is based in Salt Lake City, Utah with R&D and manufacturing operations in Maryland. For more information, please visit www.clene.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Clene's actual results may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "might" and "continues," and similar expressions are intended to identify such forward-looking statements. These forward-looking statements involve significant known and unknown risks and uncertainties, many of which are beyond Clene's control and could cause actual results to differ materially and adversely from expected results. Factors that may cause such differences include Clene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; Clene's ability to achieve commercial success for its marketed products and drug candidates, if approved; Clene's ability to obtain and maintain protection of intellectual property for its technology and drugs; Clene's reliance on third parties to conduct drug development, manufacturing and other services; Clene's limited operating history and its ability to obtain additional funding for operations and to complete the licensing or development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on Clene's clinical development, commercial and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in Clene's Annual Report filed on Form 10K, as well as discussions of potential risks, uncertainties, and other important factors in Clene's subsequent filings with the U.S. Securities and Exchange Commission. Clene undertakes no obligation to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based, subject to applicable law. All information in this press release is as of the date of this press release. The information contained in any website referenced herein is not, and shall not be deemed to be, part of or incorporated into this press release.

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