Clene Nanomedicine Announces Achievement of 50% Enrollment in the Phase 3 HEALEY ALS Platform Trial

March 9, 2021

World's first ALS platform trial led by Mass General Hospital and conducted at NEALS centers throughout the United States is a registration trial

SALT LAKE CITY, March 09, 2021 (GLOBE NEWSWIRE) -- Clene Inc. (NASDAQ: CLNN) (along with its subsidiaries, "Clene") and its wholly owned subsidiary Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company dedicated to revolutionizing the treatment of neurodegenerative disease using nanocatalysis, today announced that over 50% of participants have been enrolled in the HEALEY ALS Platform Trial being conducted at sites of the Northeast ALS (NEALS) consortium.

The HEALEY ALS Platform trial is a multi-center trial evaluating the safety and efficacy of multiple investigational products in amyotrophic lateral sclerosis (ALS) patients. It is the first ever ALS platform trial and was designed with a shared placebo arm to reduce trial time, reduce costs, and increase patient participation in developing novel therapies for ALS. It includes substantial financial support from philanthropic donors and foundations and is being implemented at up to 54 expert ALS clinical trial sites across the U.S. Clene's lead drug candidate CNM-Au8, a bioenergetic nanocatalyst, was selected by the Healey Center Therapy Selection Committee to be one of the first entrants into the trial. In the Clene, CNM-Au8 treatment regimen, a total of 160 participants are randomized 3:1 (active:placebo), with 120 randomized across two active arms (CNM-Au8 30 mg and 60mg) and 40 in placebo. Clinical data from an additional 80 placebo-treated participants are shared within the platform trial from two other regimens for an overall 1:1 allocation of active:placebo.

"Clene was honored to have CNM-Au8 chosen as one of the first drug regimens to be evaluated in the HEALEY Platform trial, and we are excited to achieve this enrollment milestone," said Robert Glanzman, MD, chief medical officer of Clene. "This trial is a testament to the excellence and hard work of our collaborators at the Sean M. Healey & AMG Center for ALS at Mass General, the research capabilities of the NEALS clinical sites, outstanding patient and caregiver support, and the dedication of our Clene colleagues in supporting this landmark study."

About CNM-Au8

Clene's lead drug candidate, CNM-Au8, a bioenergetic nanocatalyst, is a stable, aqueous suspension of catalytically active gold (Au) nanocrystals. In a patented breakthrough, clean surfaced nanocrystalline CNM-Au8 drives critical cellular bioenergetic reactions in the brain to increase cellular energy, accelerate neurorepair, and improve neuroprotection. CNM-Au8 crosses the blood-brain barrier and is not associated with the toxicities related to synthetic gold compounds or synthetic nanoparticle chemistry. CNM-Au8 is currently being evaluated in a Phase 3 registration trial in amyotrophic lateral sclerosis (ALS), a Phase 2 trial for disease progression in patients with ALS, a Phase 2 trial for the treatment of chronic optic neuropathy in patients with stable relapsing multiple sclerosis (MS), and a Phase 2 brain target engagement study in 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 multiple disease-relevant neurotoxins. Oral treatment with CNM-Au8 improved functional behaviors in rodent models of ALS, MS, and PD versus vehicle (placebo).

About the HEALEY ALS Platform Trial

The HEALEY ALS Platform trial is a perpetual multi-center, randomized, double-blind, placebo-controlled Phase 3 registration program designed to evaluate the efficacy, safety, pharmacokinetics and pharmacodynamics of multiple investigational products in early symptomatic amyotrophic lateral sclerosis (ALS) patients. Funded by philanthropic donors and led by Harvard's Massachusetts General Hospital, HEALEY is the first-ever ALS platform trial designed to reduce trial time, costs, and increase patient participation in developing novel therapies. This landmark platform trial tests multiple treatments utilizing a combined placebo group. CNM-Au8 was selected as one of the first drugs to be evaluated. Full enrollment of 160 patients into the CNM-Au8 study will occur through 54 expert ALS U.S. clinical trial sites. Subjects are randomized 3:1 to receive either active treatment or placebo daily for a 24-week treatment period. The primary endpoint is rate of change in disease severity over time as measured by the ALS Functional Rating Scale-Revised (ALSFRS-R). Secondary endpoints include change in respiratory function over time as measured by slow vital capacity and change in muscle strength over time as measured isometrically using hand-held dynamometry. For more information, please see ClinicalTrials.gov Identifier: NCT04297683.

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 recently filed registration statement on Form S-4, 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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