Clene Nanomedicine Provides Clinical Program Update

February 14, 2022

- ***Healey ALS Platform Trial fully enrolled; top-line data expected 2H 2022***
- ***Significant survival benefit from RESCUE-ALS open label extension (OLE) Phase 2 trial to be presented at upcoming Muscular Dystrophy Association (MDA) Clinical & Scientific Conference in Nashville, TN March 13-16, 2022***
- ***VISIONARY-MS to conclude early due to COVID pandemic-related challenges. Unblinded data expected 2H 2022; insights to inform new Phase 2/3 MS trial.***
- ***REPAIR-MS Phase 2 Trial initiates second cohort to confirm target engagement in non-active progressive MS***
- ***COVID-19 Phase 2 trial completes enrollment; top-line results expected mid-year 2022***

SALT LAKE CITY, Feb. 14, 2022 (GLOBE NEWSWIRE) -- Clene Inc. (NASDAQ: CLNN) along with its wholly owned subsidiary Clene Nanomedicine, Inc. (Clene) is a clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative disease. Today, Clene provided clinical program updates for its lead nanotherapeutic platform drug candidate: CNM-Au8®, as well as its antiviral candidate, CNM-ZnAg. CNM-Au8 is a gold nanocrystal suspension, developed to increase cellular energy production and utilization to restore neuronal health. CNM-ZnAg is a proprietary zinc-silver ionic solution that has demonstrated both antiviral and antimicrobial properties.

HEALEY-ALS Phase 2/3 Platform Trial on track to report top-line data in the second half of 2022
Enrollment into the HEALEY ALS Platform Trial, led by the Sean M. Healey & AMG Center for amyotrophic lateral sclerosis (ALS) at Massachusetts General Hospital (MGH), completed in November 2021. This Phase 2/3 trial is evaluating Clene's lead drug candidate, CNM-Au8, for the treatment of ALS. Top-line data are expected in the second half of this year. In anticipation of positive results, Clene is preparing for potential regulatory approval, including development of a new manufacturing facility in Maryland and commercialization planning. The U.S. Food and Drug Administration (FDA) has granted CNM-Au8 Orphan Drug designation in ALS.

Updated survival data from RESCUE-ALS OLE Phase 2 trial to be presented at upcoming MDA Clinical & Scientific Conference
Updated evidence for a long-term survival benefit with CNM-Au8 treatment from the RESCUE-ALS trial open label extension will be presented at the upcoming MDA Clinical & Scientific Conference March 13-16, 2022 in Nashville, TN. Observed survival in study participants was compared to the estimated median survival derived from the validated ENCALS prediction model with results significantly in favor of CNM-Au8 treatment.

Long-Term Expanded Access Program (EAP) treatment continues
Clene continues to support expanded access programs providing CNM-Au8 treatment at four clinical sites in over 50 participants with ALS. CNM-Au8 treatment has been well tolerated in this group of people with ALS who are not eligible for current clinical trials. Long-term use of CNM-Au8 now exceeds 2 years in these programs. Data from these EAPs will support potential regulatory filings with health authorities.

VISIONARY-MS Phase 2 Trial to conclude early due to COVID pandemic-related challenges. Unblinded results expected second half of 2022.
The VISIONARY-MS Phase 2 trial is evaluating the efficacy and safety of CNM-Au8 for remyelination and neurorepair in stable relapsing MS patients. The study has enrolled 73 of the 150 planned participants with chronic visual impairment typically treated with background disease-modifying therapy (DMT). MS patients on current DMTs typically have compromised immune systems. Consequently, MS clinical trials requiring multiple in-person clinic visits have experienced continued enrollment and operational challenges stemming from the ongoing COVID-19 pandemic and repeated viral variant waves.

Unblinded VISIONARY-MS data are targeted for the second half of 2022, with announcement of the next clinical trial in MS planned thereafter. Clene is currently working with the VISIONARY-MS trial investigators and participants to conclude the trial. Clene will utilize the available data collected from up to 48 weeks of clinical visits to better understand the efficacy and safety profile of CNM-Au8 and to inform further clinical development in MS.

"On behalf of Clene, I want to thank the investigators, site staff, and, most importantly, the participants and their families for their contribution to the VISIONARY-MS study. We will leverage the learnings from VISIONARY-MS to inform the design of our next Phase 2/3 clinicial trial in MS," said Robert Glanzman MD, Clene's Chief Medical Officer.

REPAIR-MS Phase 2 trial has been Initiated in patients with non-active, progressive MS
Following the robust target engagement results demonstrated in the REPAIR-MS Phase 2 trial in relapsing MS patients, Clene has initiated a second MS Cohort to confirm target engagement in the more severe, non-active progressive MS population. Non-active progressive MS patients currently have limited therapeutic options and high unmet need.

CNM-ZnAg Phase 2 COVID trial in Brazil completes full enrollment; top-line data expected mid-2022
Clene's Phase 2 trial of its antiviral CNM-ZnAg in acutely symptomatic, non-hospitalized COVID-19 patients has achieved full enrollment. Top-line results are expected by mid-year 2022. Clene plans to advance CNM-ZnAg into a registration trial, contingent upon positive Phase 2 results.

About the HEALEY ALS Platform Trial
The HEALEY ALS Platform Trial is a perpetual multi-center, randomized, double-blind, placebo-controlled Phase 2/3 program designed to evaluate the efficacy and safety of multiple investigational products in people living with ALS. The HEALEY ALS Platform Trial is the first-ever platform trial in ALS and was designed to reduce trial time, costs and increase patient participation in developing novel therapies. This landmark platform trial tests multiple treatments utilizing a shared master protocol and combined placebo group data. CNM-Au8 was selected as one of the first three drugs to be evaluated. Subjects are randomized 3:1 to receive active treatment or placebo for the 24-week double-blind treatment period followed by the option to enroll in the Open Label Extension in which all subjects receive active drug. 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 isometric muscle strength over time as measured using hand-held dynamometry. Top-line data are expected in 2H 2022. For more information, please see ClinicalTrials.gov Identifier: NCT04297683.

About VISIONARY-MS
VISIONARY-MS is a Phase 2 multi-center, randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of CNM-Au8 for remyelination and neurorepair in stable relapsing MS patients, with chronic visual impairment, who are allowed disease-modifying therapy. Target enrollment is 150 participants at expert MS clinical trial sites within Australia, Canada and the United States. The primary endpoint is improvement in Low Contrast Letter Acuity (LCLA) from baseline to week-24. Key secondary endpoints include improvements from baseline to week-24 in the remaining modified-Multiple Sclerosis Functional Composite (MSFC) subscales (Symbol Digit Modalities Test, 9-Hole Peg Test, and Timed 25-Foot Walk). Interim blinded data presented at the ACTRIMS Forum 2021 demonstrated exposure-dependent, statistically significant improvements in both LCLA scores and across the averaged components of the modified MSFC scale for the total study population in comparison to baseline values from the mildest sub-population ($p<0.001$). Unblinded top-line data are anticipated in the second half of 2022. For more information, see ClinicalTrials.gov Identifier: NCT03536559.

About CNM-ZnAg Phase 2 COVID Trial
This Phase 2 study, being implemented in Brazil, is a multicenter, randomized, double-blind, placebo-controlled study in acutely symptomatic, non-hospitalized patients, with moderately severe COVID-19 infection. The study randomized patients 1:1:2 to receive either a low or high dose of CNM-ZnAg or placebo in addition to standard supportive care. The primary endpoint of the study is the rate of hospitalizations at day 28, with secondary endpoints assessing time to symptom resolution.

About CNM-Au8®, a gold nanocrystal suspension
CNM-Au8 is an oral suspension of gold nanocrystals developed to restore neuronal health and function by increasing energy production and utilization. The catalytically active nanocrystals of CNM-Au8 drive critical cellular energy producing reactions that enable neuroprotection and remyelination by increasing neuronal and glial resilience to disease-relevant stressors. CNM-Au8® is a federally registered trademark of Clene Nanomedicine, Inc.

About CNM-ZnAg
CNM-ZnAg, a proprietary zinc-silver ionic solution, has demonstrated broad antiviral and antimicrobial activity.

About Clene
Clene is a clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative disease by targeting energetic failure, an underlying cause of many neurological diseases. 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 or follow us on Twitter, LinkedIn and Facebook.

Forward-Looking Statements
This press release contains “forward-looking statements” which are intended to be covered by 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 on Form 10-K, 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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