Clene Reports Significantly Decreased Mortality in RESCUE-ALS Long-Term Open Label Extension Trial

July 14, 2022

- ***As of the July 5, 2022, data cutoff, early CNM-Au8® treatment resulted in a significant survival benefit (5 CNM-Au8 deaths vs. 14 placebo deaths, HR=0.301, p=0.0143)***
- ***CNM-Au8 treatment was well-tolerated, and there were no significant safety findings reported during this open-label trial***
- ***Top-line results from HEALEY ALS Platform Trial are expected in current quarter***

SALT LAKE CITY, July 14, 2022 (GLOBE NEWSWIRE) -- Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, "Clene") and its wholly owned subsidiary Clene Nanomedicine Inc., a clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative disease, today reported significantly improved survival in ALS patients initially treated with CNM-Au8 compared to initially randomized placebo treated participants during the long-term open-label extension of its RESCUE-ALS trial.

"We are very pleased to see these results and the apparent survival benefit that our investigational drug, CNM-Au8, appears to provide to people living with ALS," said Rob Etherington, President and CEO of Clene. "At this point, we are awaiting top-line data from the HEALEY ALS Platform Trial, which focuses on endpoints measuring patient function, survival and breathing over a six-month period in a much larger cohort. Clene expects to announce these results this quarter. Based on the larger number of patients treated in the HEALEY trial and the higher dose of CNM-Au8 being tested, we are optimistic that we will be able to adequately characterize the effects of our drug on this devastating disease."

Study participants in RESCUE-ALS were randomized 1:1 to receive 30 mg of CNM-Au8 or placebo daily for 36 weeks during the double-blind portion of the study, followed by an open-label period that extended treatment up to 130 weeks from randomization. The trial enrolled 45 participants (n=23 on active treatment, and n=22 receiving placebo), and survival was compared by treatment group from randomization through the latest vital status observation with a cut-off as of July 5, 2022, for this interim analysis. Participants in the placebo-treated group, who received either no treatment or a nine-month delay in treatment initiation with CNM-Au8, were compared to participants treated daily with CNM-Au8 from randomization.

Survival data were obtained for 43 of 45 study participants, and one participant in each group was lost to follow-up. There were five deaths in the group originally randomized to CNM-Au8 and 14 deaths in the group originally randomized to receive placebo. Median survival from randomization for the CNM-Au8 group was undefined due to insufficient mortality events, and median survival for the placebo group was 23.1 months. Unadjusted Kaplan-Meier survival analyses demonstrated a significant survival benefit with participants initially randomized to CNM-Au8 treatment versus those initially randomized to placebo, resulting in a 70% decreased risk of death, log-rank hazard ratio = 0.301 (95% CI: 0.122 to 0.742, p = 0.0143). Sensitivity analyses substituting death in place of lost to follow-up censoring resulted in concordant findings (Hazard Ratio: 0.338, 95% CI: 0.143 to 0.797, p = 0.0182). The treatment was well-tolerated, and there were no significant safety findings reported during the long-term open label trial period. These data will be reported at an upcoming scientific congress.

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.

About CNM-Au8®
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.

Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, which are intended to be covered by the "safe harbor" provisions created by those laws. Clene's forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding our future operations. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would," and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements represent our views as of the date of this press release and involve a number of judgments, risks and uncertainties. We anticipate that subsequent events and developments will cause our views to change. We undertake no obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ include our ability to demonstrate the efficacy and safety of our drug candidates; the clinical results for our 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; our ability to achieve commercial success for our drug candidates, if approved; our limited operating history and our ability to obtain additional funding for operations and to complete the development and commercialization of our drug candidates; and other risks and uncertainties set

forth in “Risk Factors” in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this press release, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to rely unduly upon these statements. 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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