**Updated Interim Data from Clene Nanomedicine's RESCUE-ALS Open-Label Extension Study to be Presented in Emerging Science Program at 2022 AAN Annual Meeting**

Results show significant survival benefit in participants who entered open-label extension of study of CNM-Au8®, a gold nanocrystal suspension, compared to validated ENCALS prediction model

SALT LAKE CITY, April 1, 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 announced new data from the open-label extension of RESCUE-ALS that will be presented in a session at the 2022 American Academy of Neurology (AAN) Annual Meeting, which will take place April 2-7 in Seattle.

Featured in the Emerging Science Program on April 5, the data demonstrate a 70% survival benefit among ALS patients who entered the open-label extension of RESCUE-ALS (n=36, 90% of those eligible). This updated interim analysis of observed survival compared to estimated median survival derived from the validated ENCALS prediction model significantly favored CNM-Au8 treatment with a hazard ratio of 0.3 (corresponding to a 70% lower risk of mortality) for participants who entered the open-label extension (HR 0.3; p=0.006, log-rank test).

RESCUE-ALS was a Phase 2 multi-center, randomized, double-blind, parallel-group, placebo-controlled trial that examined the efficacy, safety, pharmacokinetics, and pharmacodynamics of CNM-Au8 in 45 participants with early ALS over a 36-week treatment period. The 36-week blinded period of RESCUE-ALS demonstrated significant benefits with CNM-Au8 treatment: slowing ALS disease progression (p=0.0125), decreasing the proportion of participants with a 6-point decline in the ALS Functional Rating Scale Revised (ALSFRS-R) (p=0.035), and improving quality of life as measured by the ALS Specific Quality of Life (ALSSQOL-SF) questionnaire (p=0.018). Furthermore, CNM-Au8 was shown to be well-tolerated with no safety signals identified over 96 weeks of treatment.

"These data are very encouraging to us in the ALS research and treatment community because they demonstrate additional evidence for improved long-term survival," said Professor Matthew Kiernan, Ph.D., DSc, FRACP, FAHMS, Bushell Chair of Neurology and Co-Director, Discovery and Translation, Brain and Mind Centre, at The University of Sydney, one of the study's clinical advisors and the presenter at AAN. "RESCUE-ALS was a proof of concept study intended to establish that treatment of neuronal energetic failure can provide disease-modifying effects in ALS. I am pleased to see the potential effectiveness of CNM-Au8 demonstrated in this study and look forward to reviewing further clinical trial data as it emerges."

Rob Etherington, Clene's CEO, added, "We will look forward to reporting results from the HEALEY ALS Platform Trial in which survival is a pre-specified key secondary endpoint. HEALEY participants will also be offered long-term, open-label extension for 52 weeks following the six-month blinded study duration, allowing for long-term assessment of survival. Our growing body of evidence from the RESCUE-ALS open label extension—and soon from the HEALEY trial—could potentially change the treatment paradigm for people living with the devastating diagnosis of ALS."

The slide presentation from the Emerging Science session will be available in the Scientific Posters & Presentations section of the Clene website on the afternoon of April 5.

**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 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 https://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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