Clene Nanomedicine Presents Updated Long-Term Survival Data from RESCUE-ALS Participants at 2022 AANEM Scientific Conference

September 21, 2022

- ***Treatment with CNM-Au8 significantly improved long-term survival with approximately a 70% decreased risk of mortality vs. original placebo randomization***
- ***Comparable survival benefits were also shown compared to ENCALS predicted median survival***
- ***C NM-Au8 treatment was well-tolerated, and there were no significant safety findings reported***

SALT LAKE CITY, Sept. 21, 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 diseases, today announced presentation of updated survival results from the Phase 2 RESCUE-ALS trial open-label extension (OLE) at the 2022 American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) Clinical & Scientific Conference, taking place September 21-24 in Nashville, Tennessee.

The poster titled, "***Evidence for a Potential Survival Benefit in Amyotrophic Lateral Sclerosis with CNM-Au8 Treatment: Interim Results from the RESCUE-ALS trial Long-Term Open Label Extension*,"** provides ongoing evidence supporting the clinical benefits of Clene's lead drug candidate, CNM-Au8®, a catalytically active gold nanocrystal suspension that holds promise as a disease-modifying therapy for amyotrophic lateral sclerosis (ALS). Specifically, the poster evaluated the survival benefit associated with long-term CNM-Au8 treatment. Updated interim analyses of all-cause mortality with up to 137 weeks of follow-up from randomization comparing participants originally randomized to CNM-Au8 to participants originally randomized to placebo demonstrated a significant survival benefit with CNM-Au8 treatment, resulting in approximately a 70% decreased risk of death (HR = 0.29, p=0.01). Sensitivity analyses of observed survival compared to predicted median survival derived from the published ENCALS prediction model based on each participant's baseline study characteristics, with a data cutoff of August 31, 2022, also demonstrated a significant survival benefit with CNM-Au8 treatment (HR = 0.36, p=0.003). CNM-Au8 treatment was well-tolerated, and there were no significant safety findings reported during the OLE.

"These clinical and survival data from RESCUE-ALS contribute to the growing body of evidence supporting the potential for CNM-Au8 as a disease-modifying therapy for amyotrophic lateral sclerosis (ALS)," said Robert Glanzman, MD, FAAN, Clene's Chief Medical Officer.

Rob Etherington, Clene's CEO, added, "The impressive ALS survival benefits seen with CNM-Au8 treatment corroborate our thesis – energetic support of neurons may protect CNS health and slow neurodegenerative disease progression. We look forward to upcoming results from the HEALEY ALS Platform Trial and advancing CNM-Au8 development in ALS and other neurodegenerative diseases, including multiple sclerosis and Parkinson's."

About Rescue-ALS
RESCUE-ALS, a Phase 2 multi-center, randomized, double-blind, parallel-group, placebo-controlled trial, examined the efficacy, safety, pharmacokinetics and pharmacodynamics of CNM-Au8 in 45 participants (73% limb onset, 27% bulbar onset) with early ALS over a 36-week treatment period. The primary endpoint was the percent change in the summated motor unit index (MUNIX) scores to week 36.

The primary blinded comparative period was followed by an open-label extension (OLE) in which all participants received 30 mg of CNM-Au8 once-daily, with 90% (36/45 patients) entering the OLE. The primary endpoint was not significant, driven by limited MUNIX decline in bulbar-onset participants. However, in a prespecified analyses of limb-onset participants who demonstrated the expected decline in MUNIX scores, there was a strong trend for reducing MUNIX scores (p=0.074). There was a significant reduction in ALS disease progression evident in CNM-Au8 treated participants at week 36 (p=0.0125), and the risk of experiencing significant (≥ 6-point) decline in ALSFRSR was significantly reduced in the CNM-Au8 treated patients (p=0.035). Furthermore, CNMAu8 treated participants demonstrated improved quality of life on the ALSSQOL-SF (p=0.018). Importantly, there were no significant CNM-Au8 related adverse effects reported.

About CNM-Au8®
CNM-Au8 is Clene's lead asset in mid- and late-stage clinical development for the treatment of multiple sclerosis and amyotrophic lateral sclerosis. An oral suspension of gold nanocrystals, CNM-Au8 was developed to protect 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 www.clene.com or follow us on Twitter, LinkedIn and Facebook.

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.

Media Contact
Ignacio Guerrero-Ros, Ph.D., or David Schull
Russo Partners, LLC
Ignacio.guerrero-ros@russopartnersllc.com
David.schull@russopartnersllc.com
(858) 717-2310

Investor Contact
Kevin Gardner
LifeSci Advisors
kgardner@lifesciadvisors.com
617-283-2856

Source: Clene Inc.

clene-logo-2x-png

Source: Clene Inc.