Clene Announces Publication of Phase 2 CNM-Au8® Clinical Data for the Treatment of ALS in LANCET's eClinicalMedicine

June 26, 2023

- ***Peer-reviewed publication includes data from the CNM-Au8 Phase 2 RESCUE-ALS trial and its open-label-extension, up to 120 weeks of patient follow-up***

SALT LAKE CITY, June 26, 2023 (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 that The Lancet's journal *eClinicalMedicine* has published combined detailed analyses of the Phase 2 RESCUE-ALS study and its open-label extension trial. The article can be accessed via the following link: https://authors.elsevier.com/sd/article/S2589537023002134.

"Results from RESCUE-ALS study were important because they provided the first insights about the clinical benefits of CNM-Au8 in ALS patients and the duration of treatment required to detect them," said Professor Steve Vucic, PhD, DSc, Northcott Chair of Neurology, The University of Sydney, and a co-investigator of the RESCUE-ALS study. "The treatment effect demonstrated a clear survival signal associated with CNM-Au8 treatment and evidence for delayed clinical worsening morbidity events such as tracheostomy and initiation of feeding tube during the double-blind placebo-controlled period. Additional functional benefits such as decreased worsening of ALSFRS-R scores are emerging later through the long-term open-label extension."

"These results corroborate the mechanism that energetic support of neurons may protect CNS health and slow neurodegenerative disease progression and are a basis for continued clinical evaluation of this promising drug candidate," said Professor Matthew Kiernan, PhD, DSc, Bushell Chair of Neurology, University of Sydney, and one of the trial's clinical advisors. "In addition, our trial explored the utility of a novel primary endpoint, MUNIX, which has advanced the state of ALS research and will help future studies of other investigational ALS treatments."

"We are pleased that CNM-Au8 results in RESCUE-ALS were concordant with the larger Phase 2b HEALEY ALS Platform Trial," said Ben Greenberg, MD FAAN, Head of Medical at Clene. "We plan to report long-term follow-up data from this program later this year and meet with the FDA in the third quarter to identify next steps for our ALS program."

About RESCUE-ALS
RESCUE-ALS was a Phase 2 multi-center, randomized, double-blind, parallel-group, placebo-controlled trial, investigating 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 of 45 patients) entering the OLE. Clene announced topline results for RESCUE-ALS on November 2, 2021.

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.

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.

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