New Data from Clene's RESCUE-ALS Study to be Presented at 2022 ENCALS Meeting

June 1, 2022

- New interim survival data from the ongoing RESCUE-ALS long-term open label extension (OLE) study demonstrate that early treatment (original randomization to active CNM-Au8) decreased risk of mortality by 62% when compared to either no treatment or delayed treatment (original randomization to placebo) (HR 0.38; p = 0.06)
- Updated interim survival data from this study also demonstrate that CNM-Au8 treatment of participants in the OLE reduced mortality risk by 64% when compared to the ENCALS predicted median survival (HR 0.36; p=0.008)
- New data from RESCUE-ALS will be presented that support CNM-Au8 effects on biomarkers of neurodegeneration and that show CNM-Au8-associated sustained long-term improvements in quality of life
- Preclinical data will be presented that support catalytically-active gold nanocrystals of CNM-Au8 as a promising new therapeutic strategy for the treatment of ALS

SALT LAKE CITY, June 01, 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 the presentation of new data from the company's Phase 2 RESCUE-ALS study at the European Network to Cure ALS (ENCALS) Meeting 2022 taking place June 1-3 in Edinburgh, Scotland.

Clene will host at the conference five poster presentations about clinical and preclinical investigations of CNM-Au8, a new drug being developed as a potential disease-modifying treatment for the fatal neurodegenerative disease amyotrophic lateral sclerosis (ALS).

Poster 1: CNM-Au8 Gold Catalytic Activity Protects Neurons Against Degeneration and Death in Multiple in vitro Models of Amyotrophic Lateral Sclerosis

- Preclinical evidence for neuroprotection by CNM-Au8, using both human induced pluripotent stem cell and primary neural-glial models of ALS, indicate that catalytically-active gold nanocrystals of CNM-Au8 target energy metabolism by a novel mechanism holds promise as a new therapeutic strategy for the treatment of ALS.

Poster 2 : Evidence for a Potential Survival Benefit in ALS with CNM-Au8 Treatment: Interim Results from the RESCUE-ALS Trial Long-Term Open Label Extension

- Important, newly released interim survival data from the long-term open label extension study demonstrate that early treatment (original randomization to active CNM-Au8) decreased risk of mortality by 62% when compared to delayed treatment (original randomization to placebo) (HR 0.38; p = 0.06); and decreased mortality risk by 64% when participant survival is compared to individual participant ENCALS predicted median survival (HR 0.36; p=0.008).

Poster 3: RESCUE-ALS Trial Results: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of CNM-Au8 to Slow Disease Progression in ALS

- The results from the RESCUE- ALS study provide evidence of safety and suggest efficacy of CNM-Au8 in patients with early ALS. The 36-week blinded period of RESCUE-ALS suggested efficacy benefits with CNM-Au8 treatment versus placebo: 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).

Poster 4: Interim ALS Specific Quality of Life Results from the Long-Term Open Label Extension of RESCUE-ALS, a Double-Blind, Placebo-Controlled Study of CNM-Au8 to Slow Disease Progression in ALS

- CNM-Au8 treatment resulted in improved quality of life assessed by the ALS Specific QOL short-form scale [ALSSQOL-SF), (p=0.018) during the 36-week double-blind period). Furthermore, during the OLE, subjects originally randomized to CNM-Au8 continued to maintain stable ALSSQOL-SF scores through 84 weeks or more of treatment. Ex-placebo participants who transitioned to the CNM-Au8 treatment during the long-term OLE demonstrated similar stability.

Poster 5: Preliminary Biomarker Findings from the RESCUE-ALS Double-Blind, Placebo-Controlled Study of CNM-Au8 to Slow Disease Progression in ALS

- CNM-Au8 treated participants in the RESCUE-ALS study demonstrated decreased levels of markers of neurodegeneration, specifically plasma ubiquitin C-terminal hydrolase L1 and urinary neurotrophin receptor p75 extracellular domain normalized to creatine levels, compared to placebo over the 36-week double-blind period.

“These emerging data highlight the significantly reduced risk of mortality following early and sustained treatment with CNM-Au8.,” said Rob Etherington, President and CEO of Clene. “The magnitude of the effect, more than 60% reduction in risk versus delayed treatment, provides hope for people with ALS and their caregivers. Based on these emerging survival data, the RESCUE-ALS open-label has been extended indefinitely, and we are excited to understand how CNM-Au8 treatment may continue to keep people with ALS alive and with stable quality of life.”

Dr. Robert Glanzman, Clene’s Chief Medical Officer, said, “As we continue to perform preclinical experiments in collaboration with academic partners and analyze the enriching dataset from RESCUE-ALS, the data consistently highlight CNM-Au8 as an emerging therapeutic option for people with this devastating disease. We look forward to the next major data readout from the HEALEY ALS platform trial that is expected in the third quarter.”

The posters will be available on-demand via the conference portal and on the Posters and Presentations section of the Clene website beginning at 7 a.m. EDT today.

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” 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. 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 substantial dependence on the successful commercialization of our drug candidates, if approved, in the future; 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;, our ability to achieve commercial success for our drug candidates, if approved; our ability to obtain additional funding for operations; the effects of inflation; the effects of staffing and materials shortages; the possibility that we may be adversely affected by other economic, business, and/or competitive factors; 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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