Clene Presents New Clinical Data at ECTRIMS 2025 Meeting Demonstrating CNM-Au8® Improves Brain Energy Metabolism in Multiple Sclerosis Patients

September 25, 2025

- ***Late-breaking clinical data presented at the 41st Congress of the European Committee for Treatment and Research in Multiple Sclerosis***
- ***Across non-active progressive MS (primary progressive and secondary progressive MS), relapsing MS, and Parkinson's disease patients, CNM-Au8 ® improved the brain's energy metabolism evidenced by improved NAD+/NADH ratio***
- ***At the Type B end-of-Phase 2 MS meeting with the U.S. Food and Drug Administration, FDA aligned with Clene acknowledging the limitations of the Expanded Disability Status Scale and expressed openness to considering other potential primary endpoints, including cognition, to evaluate broader treatment effects***

SALT LAKE CITY, Sept. 25, 2025 (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 improving mitochondrial health and protecting neuronal function to treat neurological diseases, including amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS), today announced the presentation of the combined REPAIR-MS results across relapsing MS and non-active progressive MS during the 41st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), held September 24-26, 2025, in Barcelona, Spain.

The REPAIR studies, including REPAIR-MS and REPAIR-PD, were Phase 2, open label, sequential group, investigator blinded studies of magnetic resonance spectroscopy (^{31}P-MRS) to assess the effects of CNM-Au8 on the bioenergetic improvement impaired neuronal redox state. Participants received 12 weeks of CNM-Au8, followed by a 6-week post-therapy safety follow up (REPAIR-MS). The primary endpoint was the change in brain NAD+/NADH ratio—a measure of energetic capacity—from baseline to week 12.

Participants analyzed for the primary efficacy outcome (all evaluable with post-baseline scans at the Week 12 visit) included REPAIR-MS Cohort 1 (relapsing MS, n=11), REPAIR-MS Cohort 2 (non-active progressive MS, n=15), and REPAIR-PD (n=13) in prespecified analyses across the overall population (total n=39).

Key findings from CNM-Au8 treatment include:

- The mean NAD+/NADH ratio in the brain was significantly increased following 12 weeks of treatment with CNM-Au8 in the full REPAIR population (+0.449 units, 95% CI: 0.093 to 0.805, p=0.0148; percent change: 8.65%, 95% CI: 2.6% to 14.7%, p=0.0006).
- The change in REPAIR-MS participants alone demonstrated consistent increases in the NAD+/NADH ratio to Week 12 (+0.480 units, 95% CI: -0.018 to 0.979, p=0.058; percent change: +9.49%, 95% CI: 1.14% to 17.85%, p=0.0275), a measure of how efficiently the brain makes energy.
- Secondary endpoints: the change in the % fraction of brain NAD+ and NADH similarly demonstrated statistically significant increases in NAD+ and decreases in NADH for both the full REPAIR population (p=0.0058) and REPAIR-MS (p=0.0232), respectively.

Striking relationships between MS disease activity and brain energy metabolic indices were present at the pre-treatment baseline visit.

- The Expanded Disability Status Scale (EDSS), a global measure of MS disease severity, was significantly associated with the baseline deficits in the NAD+/NADH ratio (Pearson Correlation: ρ=-0.429, p=0.0127).
- Baseline measures of working memory and cognitive processing speed, measured by the Symbol Digit Modalities Test, were significantly associated with average brain ATP levels (peak signal area average for α-ATP, β-ATP, γ-ATP; Pearson Correlation: ρ=0.542, p=0.0009).
- Baseline measures of upper extremity function, measured by the 9-Hole Peg Test time (total time across hands), was also significantly associated with average brain ATP levels (peak signal area average for α-ATP, β-ATP, γ-ATP; Pearson Correlation: ρ=-0.513, p=0.0032).

Collectively, these data reinforce the insight that bioenergetic failure in the brain is a key contributor to neurodegeneration and disease progression in MS. By improving brain energy metabolism, CNM-Au8 may help slow progression of disability.

CNM-Au8 treatment was safe and well tolerated with treatment emergent adverse events characterized as transient and predominantly mild-to-moderate in severity.

“CNM-Au8 was able to demonstrate an improvement in metabolic profiles in the brain over 12 weeks, highlighting the potential of CNM-Au8 to address key energy deficits in the brain,” said Benjamin Greenberg, MD, Head of Medical at Clene. “These results not only demonstrate a direct correlation of brain bioenergetics with disability, but they also demonstrate the ability of CNM-Au8 to ‘rescue’ this deficit. Further analysis is ongoing to tell us more about progressive MS and may show how targeting brain bioenergetics can treat MS as well as other neurodegenerative disorders.”

“We are grateful to the patients with MS and Parkinson’s disease who participated in this clinical research,” said Rob Etherington, CEO of Clene. “These promising clinical results strengthen the body of evidence supporting further clinical development of CNM-Au8 for the treatment of MS. Additionally, the openness from the FDA to discuss disability outcome measures beyond the EDSS, such as cognition and other broader treatment effects, marks a new milestone for MS clinical trials.”

About Clene

Clene Inc., (Nasdaq: CLNN) (along with its subsidiaries, “Clene” and its wholly owned subsidiary Clene Nanomedicine, Inc.), is a late clinical-stage biopharmaceutical company focused on improving mitochondrial health and protecting neuronal function to treat neurodegenerative diseases, including amyotrophic lateral sclerosis, Parkinson’s disease, and multiple sclerosis. CNM-Au8 ® is an investigational first-in-class therapy that improves central nervous system cells’ survival and function via a mechanism that targets mitochondrial function and the NAD pathway while reducing oxidative stress. CNM-Au8® is a federally registered trademark of Clene Nanomedicine, Inc. 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 X (formerly Twitter) and LinkedIn.

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 general market conditions, whether clinical trials demonstrate the efficacy and safety of our drug candidates to the satisfaction of regulatory authorities, or do not otherwise produce positive results which may cause us to incur additional costs or experience delays in completing, or ultimately be unable to complete the development and commercialization 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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