Clene Presents Evidence of Remyelination and Neuronal Repair With CNM-Au8® Treatment At the American Academy of Neurology Late-Breaking Science Session

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- ***Analyses of MRI and VEP data confirm anatomical and physiological improvements, indicating remyelination and neuronal repair in the brains of MS patients treated with CNM-Au8 during the long-term extension of VISIONARY-MS***
- ***Over 90% of participants who showed improvements in cognition and vision also demonstrated corresponding improvements on MRI and visual electrophysiology tests***

SALT LAKE CITY, April 08, 2025 (GLOBE NEWSWIRE) -- Clene, Inc. (Nasdaq: CLNN) and its subsidiary, Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company dedicated to advancing therapies for neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS), today announced new evidence of remyelination and neuronal repair in MS participants following treatment with CNM-Au8® 30 mg from analyses of the VISIONARY-MS Trial long-term open-label extension study. The *post hoc* analyses identify consistent anatomical and physiologic effects within the same study participants resulting in cognition and vision improvement for people living with MS.

The presentation at the AAN 2025 Annual Meeting (San Diego, CA) today in the Late Breaking Science Session 2, “Physiologic and Anatomical Evidence of Neuronal Repair and Remyelination from the Long-Term Open-Label Extension of the Phase 2 VISIONARY-MS Trial,” **highlights significant and clinically meaningful improvements in cognition and visual function, supported by corresponding objective biomarkers**, including advanced MRI Diffusion Tensor Imaging (DTI) and multi-focal Visual Evoked Potential (mf-VEP) assessments.

Key findings from the analyses of the long-term VISIONARY-MS trial extension included:

- **MRI DTI metrics** (Axial Diffusivity (AD) and Magnetization Transfer Ratio (MTR) —structural markers associated with neuronal repair and remyelination) **confirmed improvements in the brain’s neuronal structure consistent with remyelination and repair** among MS participants receiving CNM-Au8
- **mf-VEP metrics** (VEP latency and amplitude—functional markers associated with remyelination and neuronal repair) **confirmed improvements in the visual system and related to cognitive function** among MS participants receiving CNM-Au8

Both the **LCLA (low contrast letter acuity) vision** —a visual measure associated with vision-specific quality of life and overall MS disability**and SDMT (symbol digit modality test)** —a benchmark for working memory and cognitive processing speed in MS **improved in CNM-Au8 participants, results that have not been previously documented in MS clinical trials** of other repair candidate drugs.

Importantly, these clinical improvements correlated with objective biomarker measurements including:

- **96% of participants who were LCLA responders, showing visual improvement,** also demonstrated improvement in MRI DTI metrics (AD and/or MTR), **evidencing repair and remyelination**
- **91% of LCLA visual responders exhibited mf-VEP Improvements in Latency (conduction velocity) and/or Amplitude (signal strength)**
    - VEP provides an objective measure of visual circuit pathway, further supporting functional recovery linked to repair and remyelination
- **98% of SDMT** responders with improved cognition had corresponding improvements in MRI DTI AD and/or MTR metrics, **substantiating that the cognitive enhancement** was associated with repair and remyelination

These results are also consistent with previous neuronal and clinical improvement observed in the double-blind period of the VISIONARY-MS trial, while also reinforcing the long-term benefits of the novel therapeutic mechanism of CNM-Au8. CNM-Au8 supports critical repair processes within neurons and oligodendrocytes, leading to improved neurological function and remyelination, as previously documented.

“For years there have been attempts to test potential remyelination therapies in MS with little to no success. Even for interventions that yielded nominal changes in MRI or physiology measures, there was a lack of consistent, robust clinical benefits to participants. These results underscore the fact that CNM-Au8 treatment in the Phase 2 VISIONARY-MS Trial not only led to clinical improvements, but also demonstrates that these observed clinical benefits resulted from underlying tissue repair and evidence of remyelination,” stated Ben Greenberg, MS expert and Head of Medical for Clene. “We look forward to confirming these data in a global Phase 3 trial.”

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 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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