Evidence for Clene's CNM-Au8® as a Treatment for Repair and Remyelination in Multiple Sclerosis Presented in the Emerging Science Session at the 2024 American Academy of Neurology Annual Meeting

April 16, 2024

- Long term extension of the Phase 2 VISIONARY-MS clinical trial of CNM-Au8 demonstrated significant evidence of repair and remyelination across multiple paraclinical endpoints (change from original baseline, p<0.05)
- Significantly improved clinical outcomes associated with long-term daily oral CNM-Au8® 30 mg treatment (change from original baseline; p<0.05)
- Long-term CNM-Au8 treatment, encompassing up to three years, was well-tolerated; no significant safety findings were observed
- First Phase 2 clinical MS trial of a non-immunomodulatory drug to meet a clinical outcome of improved function supporting remyelination and reparative effects

SALT LAKE CITY, April 16, 2024 (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 neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS), presented the Phase 2 VISIONARY-MS long term extension (LTE) study results at the 2024 American Academy of Neurology (AAN) Annual Meeting in Denver.

During the Emerging Science Session, Dr. Michael Barnett, MBBS, FRACP, FRCP, PhD, from the University of Sydney, presented data demonstrating improved clinical, functional, and structural outcomes associated with daily oral dosing of CNM-Au8 30 mg for up to three years of treatment.

These new long-term results from the Phase 2 VISIONARY-MS clinical trial demonstrated evidence supporting repair and remyelinating effects of CNM-Au8 treatment in patients originally randomized to CNM-Au8. The long-term results further enhance the trial's findings from the double-blind period, which demonstrated significant improvements on low contrast letter acuity and on the modified MS Functional Rating Scale, the study's primary and secondary endpoints, with continued improvement observed in the LTE.

The significant and concordant results across multiple paraclinical exploratory endpoints reinforce the evidence for sustained clinical benefit to study participants across multiple clinical outcome measures, associated with consistent improvements in neuronal function and remyelination.

"Phase 2 CNM-Au8 VISIONARY-MS Trial: Long-Term Extension Results" presentation key highlights:

Clinical improvements in cognition and vision

- Participants originally randomized to CNM-Au8 treatment experienced continued significant improvement in vision as measured by low contrast letter acuity. More than half of participants improved by 10 or more letters on a low-contrast Sloan eye chart, with increases of up to 38 letters (mixed model repeat measures, or MMRM vs. original baseline, $p < 0.001$).
- Participants originally randomized to placebo who transitioned to CNM-Au8 after the 48-week double blind period into the open label extension also experienced significant improvement in vision as measured by low contrast letter acuity following treatment with 30 mg CNM-Au8 (MMRM vs. original baseline, $p < 0.05$).
- Study participants treated with CNM-Au8 experienced up to 29 points of significant improvement (max score =110) in cognition and working memory as measured by the Symbol Digit Modality Test (SDMT) (MMRM vs. original baseline, $p < 0.001$).

Physiologic functional evidence of repair and remyelination

- Study participants treated with CNM-Au8 experienced significant improvements in both amplitude (MMRM vs. original baseline, $p < 0.01$) and latency (MMRM vs. original baseline, $p = 0.06$) as measured by multi-focal visual evoked potentials, physiologic measures of signal strength and speed along the visual pathway, markers of neuronal health and remyelination, respectively.

Structural evidence of repair and remyelination

- MRI measures of axial diffusivity showed significant improvements in T2 brain lesions in study participants treated with CNM-Au8 (MMRM vs. original baseline, $p < 0.05$).
- MRI measures of T2 lesion myelin water fraction (MWF) and magnetization transfer ratio (MTR), markers of remyelination, improved with long-term CNM-Au8 treatment (MWF: MMRM vs. original baseline, $p < 0.05$; MTR: MMRM vs. original baseline, $p = 0.06$).

CNM-Au8 was well-tolerated, and no significant safety findings were observed.

“The development of adjunctive therapies that not only prevent neurodegeneration, but also improve neuronal function with measurable clinical benefit, will fill a major unmet need for people living with MS. In the VISIONARY-MS trial, consistent improvements in multiple clinical and paraclinical endpoints over three years of adjunctive treatment with CNM-Au8 provide clear impetus for a definitive Phase 3 study,” stated Dr. Barnett.

Dr. Benjamin Greenberg, Head of Medical for Clene, noted, “Observing such a profound clinical benefit with corresponding improvements in physiologic measures utilizing a mechanism that does not target immune system modulation has never been demonstrated in prior multiple sclerosis trials. This is a very exciting data set that gives hope to the millions of people who are suffering from this disabling disease.”

The presentation is available in the Presentations section of the Clene website.

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 and LinkedIn.

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,” “could,” “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 clinical trials of our drug candidates may fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities, or may 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; changes in government regulation or in practices relating to the pharmaceutical and biotechnology industries, including potential healthcare reform, could decrease the need for our drug candidates, or make it more difficult to obtain regulatory approvals for our drug candidates and commercialize them; we depend substantially on the successful commercialization of our drug candidates in the future, which may fail to materialize or may experience significant delays; we have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance; and our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations, which may not be available on acceptable terms, or at all, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce, or terminate our drug development or commercialization efforts; 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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