Clene Presents Clinical Results of CNM-Au8® 30mg Treatment From Visionary-MS Trial Long-Term Extension at Annual ACTRIMS Forum 2024

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- Long-term CNM-Au8 treatment demonstrated significant and clinically meaningful improvement of vision as measured by low contrast letter acuity (LCLA), an assessment of visual function in people living with multiple sclerosis (MS), through 35 months from randomization, p<0.0001
- Long-term CNM-Au8 treatment demonstrated improvement of cognition, measured by the Symbol Digit Modality Test (SDMT), through 35 months from randomization, p<0.0001
- Treatment was well-tolerated, without a single serious adverse event attributed to CNM-Au8 and no significant safety findings were reported

SALT LAKE CITY, Feb. 29, 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 (ALS) and multiple sclerosis (MS), today presented full clinical results for CNM-Au8® from the VISIONARY-MS Trial long-term open label extension (LTE) in participants with stable relapsing multiple sclerosis (RMS) totaling nearly three years of follow-up at the ninth annual Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum in West Palm Beach, Florida.

The data presentation, titled “***CNM-Au8 VISIONARY-MS Trial | Long Term Extension Clinical Results***,” includes clinical results from the VISIONARY-MS Phase 2 long-term open label extension in participants with stable relapsing multiple sclerosis (RMS) and chronic optic neuropathy who received background immunomodulatory disease-modifying therapy (DMT). After completion of the double-blind period, 55 of 69 (80%) LTE-eligible study participants continued on CNM-Au8 30mg for up to an additional 96 weeks. Analyses are reported for the modified intent to treat (mITT) population including all study participants with valid clinical data.

In participants originally randomized to CNM-Au8, continued long-term treatment demonstrated **significant improvement of vision** as measured by low contrast letter acuity (LCLA) through 35 months from randomization, p<0.0001.

- The least-square mean difference (SE) at Week 144 for LCLA change across both eyes versus the original randomization baseline of participants assigned to CNM-Au8 was: +8.70 letters (1.88), 95% CI: 5.0 to 12.4, p<0.0001.
- Low contrast vision demonstrated sustained improvement by up to 38 letters across both eyes in individual participants, representing clinically meaningful multiple row gains on a greyed-out MS eye chart.

Long-term CNM-Au8 treatment similarly demonstrated **significant improvement of global neurological function** measured by the modified MS Functional Composite (mMSFC) scale through 35 months from randomization, p=0.018. The mMSFC scale evaluates low contrast vision, cognition, upper extremity function, and walking speed as a combined mean standardized change.

- The least-square mean difference (SE) at Week 144 for mMSFC change versus the original randomization baseline of participants assigned to CNM-Au8 was 0.65 (0.275), 95% CI: 0.11 to 1.20, p=0.018.
- Sustained improvement by up to 1.4 units was observed in individual participants, which represents a return of function.

Significant improvements in cognition and working memory, measured by the symbol digit modalities test (SDMT), were also observed following long-term CNM-Au8 treatment through 35 months from randomization, p<0.0001.

- The least-square mean difference (SE) at Week 144 for SDMT change versus the original randomization baseline of participants assigned to CNM-Au8 was 8.03 points (1.52), 95% CI: 5.01 to 11.0, p<0.0001.
- SDMT also demonstrated clinically significant sustained improvement by up to 29 points in individual participants.

CNM-Au8 was safe and well-tolerated during the LTE. Treatment emergent adverse events (TEAEs) were transient and predominantly mild-to-moderate; the most common TEAEs included: upper respiratory infection (%), headache (%), and urinary tract infection (%). Overall average treatment compliance was 94% (bottles consumed/bottles dispensed).

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 VISIONARY-MS

VISIONARY-MS, designed to investigate the protection or improvement of neurological function in stable relapsing remitting MS participants with chronic optic neuropathy, was a Phase 2 multi-center, randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of CNM-Au8 (15 mg or 30 mg daily) versus placebo over 48 weeks of double-blind treatment. The primary outcome was LCLA improvement. Global neurological improvement, measured by the modified Multiple Sclerosis Functional Composite (mMSFC) including vision, cognition, upper extremity function, and walking speed assessment was the secondary outcome. Nearly all participants (92%) were treated with highly effective immunomodulatory disease modifying therapies (DMTs) as background standard of care. In the double-blind portion of the trial, 73 participants were randomized, with 55 of 69 eligible (80%) participants continuing in the LTE. For more information, see ClinicalTrials.gov Identifier: NCT03536559.

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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