Clene Presents Extended Survival Data Through 3.5 Years and New NfL Responder Results with CNM-Au8® 30 mg Treatment from the HEALEY ALS Platform Trial Open Label Extension at the 2024 ENCALS Meeting

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- *Survival analyses with CNM-Au8 30 mg treatment compared to matched PRO-ACT controls demonstrated* ***improved survival up to 3.5 years post-baseline (hazard ratio: 0.431, p=0.0002)***
- ***Average of 28% NfL reduction observed in an NfL responder subset*** *(geometric mean ratio, change at Week 76 post-baseline: 0.72, p<0.0001)*
- *More than 650 patient years of CNM-Au8 treatment exposure without any identified safety signals*

SALT LAKE CITY, June 18, 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), today presented new long-term CNM-Au8 treatment results for survival and neurofilament light (NfL) levels from the HEALEY ALS Platform Trial open label extension (OLE) at the European Network for the Cure of ALS (ENCALS) meeting in Stockholm, Sweden.

The data presentation, titled “***Long-Term CNM-Au8 Treatment Reduces Neurofilament Light Levels and Improves Survival: Results from the HEALEY ALS Platform Trial***,” highlights up to 42 months (3.5 years) of survival follow-up and 76 weeks of long-term NfL biomarker results, including a responder subset from the HEALEY ALS Platform Trial in participants with ALS. All participants treated with CNM-Au8 30 mg, including ex-placebo participants who transitioned to CNM-Au8 in the OLE, with complete baseline co-variates were included in the survival analysis.

Improved Survival Compared to Matched PRO-ACT Controls:

Survival analyses of participants originally randomized to CNM-Au8 30 mg treatment (n=59) and ex-placebo to CNM-Au8 (n=11) compared to matched PRO-ACT controls up to 3.5 years post-baseline.

- **Approximately 60% decreased risk of death in CNM-Au8 30 mg treated patients compared to matched PRO-ACT controls up to** 3.5 years of follow-up; covariate-adjusted hazard ratio: 0.431 (95% CI: 0.276-0.672), **p-value = 0.0002**

Reduced Neurofilament Light Biomarker Levels (NfL) in NfL Responders:

NfL Responder Subset: The NfL responder analysis was completed to identify NfL decreases in participants who showed consistent NfL declines (n=55). Responders were defined as participants who had all post-baseline measures with an NfL decrease or repeated declines of at least 10 pg/mL following the start of CNM-Au8 treatment:

- **Responders demonstrated an average NfL reduction of 28%, which is suggestive of decreased axonal loss on an ongoing basis**; GMR at Week 76 change vs. baseline: 0.72, (95% CI: 0.67 – 0.79), p<0.0001

The NfL results are based on earlier announced analyses of plasma NfL collected from participants (n=99) in the HEALEY OLE who were treated with CNM-Au8 30 mg through week 76 compared to participants treated with placebo for 24 weeks prior to crossing over to active treatment for up to 52 weeks. Long-term treatment with CNM-Au8 30 mg resulted in continued significant decline of plasma NfL levels. The geometric mean ratio (GMR) vs. placebo at week 76 was 0.841, 95% CI: 0.73 – 0.98, p=0.023.

CNM-Au8 was safe and well-tolerated during the OLE.

Benjamin Greenberg, M.D., Head of Medical at Clene, said, “The clinical evidence of plasma neurofilament reduction, as well as the long-term improved survival results up to 3.5 years compared to an established multi-study ALS dataset of more than 12,000 patients across multiple clinical centers provides further evidence to strongly support CNM-Au8 as a potential treatment for ALS.”

The poster is now available in the Scientific Posters & 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 (formerly Twitter) 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," "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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