# Clene Provides Regulatory Update Following Constructive FDA Type-C Meeting on Neurofilament Biomarker Analysis Plan and Confirms Two Additional FDA Meetings

June 30, 2025

- ***FDA provides supportive feedback on proposed statistical analysis plan for neurofilament biomarker analysis of Clene's NIH-sponsored Expanded Access Program***
- ***NfL EAP biomarker analyses to be conducted early in the 4th Quarter of 2025***
- ***Clene confirms two additional FDA meetings scheduled for 3rd Quarter of 2025, to discuss ALS survival data and MS clinical development program***
- ***Submission of new drug application for ALS under the accelerated approval pathway on track for potential submission in the 4th Quarter of 2025***

SALT LAKE CITY, June 30, 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 provided a regulatory update following a Type C meeting with the U.S. Food and Drug Administration (FDA), and announced two additional meetings scheduled with the FDA in the 3rd quarter of 2025.

In the recently concluded Type C meeting, Clene discussed its proposed statistical analysis plan (SAP) for comparing neurofilament light (NfL) biomarker data from its ongoing NIH-sponsored Expanded Access Protocol (EAP), supporting nearly 200 people living with ALS treated with compassionate use of CNM-Au8®, to matched ALS controls. The FDA provided constructive feedback on Clene's proposed analysis methodology for assessing NfL change. NfL change will be analyzed following 9 months of treatment (primary NfL analysis) and after 6 months of treatment (supportive NfL analysis). These analyses are planned to provide supportive data of the NfL change demonstrated in the HEALEY ALS Platform Trial double-blind period following 6 months of treatment with CNM-Au8.

The Agency's acceptance of the SAP, expected this summer, will establish an agreed upon framework for analyses of NfL change in EAP participants. Clene has already resubmitted its revised SAP incorporating FDA's requested revisions. The NfL analyses will be conducted early in the 4 th quarter of 2025. If the findings demonstrate a clinically meaningful decline in NfL, they may support a new drug application (NDA) submission under the accelerated approval pathway, planned for the end of 2025.

The FDA has also confirmed two additional meetings with Clene scheduled for the 3rd quarter of 2025:

- **ALS Survival Data Type C Meeting**: This meeting will review the long-term survival benefit from CNM-Au8 30 mg treatment compared to concurrently randomized controls from another Healey ALS Platform Trial Regimen, assessing whether these data support filing of an NDA under an accelerated approval pathway.
- **End-of-Phase 2 Type B MS Program Meeting:** This meeting will review results from the Phase 2 VISIONARY-MS trial and discuss the planned Phase 3 study focusing on cognition improvement as an adjunct to standard-of-care MS therapies, addressing a critical unmet medical need for people struggling with MS.

"We are encouraged by the FDA's collaborative approach and their constructive feedback on our NfL biomarker analysis plan from the ongoing NIH-sponsored EAP program," said Benjamin Greenberg, MD, Head of Medical at Clene. "With two additional FDA meetings scheduled to discuss long-term ALS survival results and the End-of-Phase 2 MS results, we are advancing our ALS and MS programs to deliver an innovative therapy for people living with neurodegenerative diseases."

**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 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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