Clene Announces Plans to Submit Briefing Book to the U.S. Food and Drug Administration in Connection with Granted Type C Interaction to Obtain FDA Feedback on Potential Pathway to Accelerated Approval for CNM-Au8® in ALS

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SALT LAKE CITY, July 11, 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 announced plans to submit a briefing book by July 13 to the U.S. Food and Drug Administration (FDA) in advance of a granted Type C interaction. The purpose of the interaction with the FDA, to occur in the third quarter of 2024, is to receive feedback on the potential path to submission of a new drug application (NDA) for CNM-Au8® as a potential treatment for ALS via the accelerated approval pathway.

Clene’s briefing book contains new post-hoc analyses of data from completed clinical studies and is designed to address comments from the FDA made in a prior meeting announced publicly in December 2023, and in which Clene obtained feedback regarding the potential for accelerated approval. The briefing book contains additional analyses of neurofilament light (NfL) biomarker reduction, a more matured set of survival and functional benefit data, and additional evidence of CNM-Au8’s potential mechanism of action, which Clene believes collectively support accelerated approval based on NfL reduction as a surrogate endpoint. Clene believes these new analyses serve to further demonstrate the potential for CNM-Au8 as a treatment in people living with ALS, consistent with the accelerated approval standards. Clene also included data addressing the agency’s request to provide additional information concerning the relationship between CNM-Au8’s proposed mechanism of action and reduction in NfL, as well as the association between observed NfL reductions and improved clinical outcomes in ALS patients, including survival.

Further insights into these new data analyses will be presented publicly later in 2024.

Clene plans to publicly announce the topline FDA feedback following the conclusion of the Type C interaction.

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 the Company’s expectations, hopes, beliefs, intentions or strategies, including expectations regarding the timing of the Type C meeting, the timing of the Company’s publication of the FDA’s topline comments, and the timing of the publication of additional data. In addition, any statements that refer to 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, the Company’s expectations, hopes, beliefs, intentions or strategies, including expectations regarding the timing of the Type C meeting, the timing of the Company’s publication of the FDA’s topline comments, and the timing of the publication of additional data, may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ include the Company’s ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its 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; the Company’s ability to achieve commercial success for its drug candidates, if approved; the Company’s limited operating history and its ability to obtain additional funding for operations and to complete the development and commercialization of its 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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