Clene Granted In-Person Meeting With FDA Senior Leadership to Discuss CNM-Au8 Biomarker and Related Clinical and Survival Data

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SALT LAKE CITY, Sept. 16, 2024 (GLOBE NEWSWIRE) -- Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, “Clene”) and its wholly owned subsidiary Clene Nanomedicine Inc., a late 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), announced today that it will meet in-person with the U.S. Food and Drug Administration (FDA) before the end of November 2024 to discuss CNM-Au8 development for ALS.

The meeting will include the FDA’s Director of the Office on New Drugs, the Director of the Office of Neuroscience, and the Division of Neurology 1 (DN1) review team, as well as recognized key opinion leaders in ALS, biostatistics, and biomarkers. Clene is appreciative of the FDA’s use of process and regulatory flexibility to obtain the best outcome for people living with ALS.

By way of background, days prior to DN1 granting the in-person meeting, DN1 communicated that Clene’s briefing package for CNM-Au8 was not supportive of an NDA submission under the accelerated approval pathway. However, after further dialogue, the FDA agreed to meet in person to re-evaluate Clene’s submission under the accelerated approval pathway. Clene looks forward to the opportunity to have experts present their views to the FDA and address questions on ALS biomarkers, related clinical endpoints, and survival data, all of which Clene believes are essential for the understanding of its CNM-Au8.

For CNM-Au8, Clene has more than 700 patient-years of safety data that show no significant safety concerns or safety trends identified. No serious adverse events (SAEs) have been identified as related to CNM-Au8 treatment by any clinical trial investigators to date.

About Clene
Clene 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.

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 the timing of the interaction with the FDA. 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. 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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