Clene Provides Update on ALS Clinical Development Meeting With FDA

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SALT LAKE CITY, Dec. 21, 2023 (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 provided an ALS regulatory update from its recent meeting with the U.S. Food and Drug Administration (FDA).

Clene met with the FDA to discuss CNM-Au8® for the treatment of ALS, presenting initial clinical and Neurofilament Light Chain (NfL) biomarker results from the completed Phase 2 ALS studies. Clene also presented the evidence of long-term survival data from these studies as well as the supportive safety data of more than 500 years of participant exposure to date without any identified safety signals across ALS, MS, and Parkinson’s disease.

The FDA determined that the initial findings on biomarker NfL reduction from the Phase 2 programs were insufficient to support accelerated approval at this time. Clene is looking forward to providing supplemental data for further engagement with the FDA in the first half of 2024, including additional long-term clinical evidence and biomarker results of CNM-Au8’s treatment benefit in people living with ALS. Clene plans to demonstrate how CNM-Au8’s mechanism of action is linked to the reduction in NfL, and the association between observed NfL reductions and improved clinical outcomes in ALS patients, including increased survival time.

“As we continue to analyze the data from our Phase 2 clinical program, we believe the evidence supports that CNM-Au8 treatment improved survival in people living with ALS,” said Benjamin Greenberg, M.D., Clene’s Head of Medical. “We are also encouraged that the recently disclosed long-term NfL biomarker decreases are consistent with delayed clinical time-to-event outcomes.”

Rob Etherington, CEO of Clene, said, “Clene is committed to people living with ALS. We presently support two ongoing CNM-Au8 compassionate use (expanded access) programs and are shortly commencing a third compassionate use program that is supported by a $45.1M grant from the National Institutes of Health. In addition, we anticipate launching the Phase 3 ALS confirmatory study in 2024. Importantly, we also plan to submit new information to the FDA for further discussions on the totality of evidence in order to advance the accelerated development of CNM-Au8 for the treatment of ALS.”

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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