Clene Awarded Grant From National Multiple Sclerosis Society to Advance Development of CNM-Au8® in Non-Active Progressive Multiple Sclerosis

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SALT LAKE CITY, May 25, 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 revolutionizing the treatment of neurodegenerative disease, today announced that Clene has received a grant from the National Multiple Sclerosis Society (NMSS) via the organization’s Fast Forward Program, a competitive, expert-reviewed funding opportunity to support commercial organizations that are developing new therapies for the treatment of multiple sclerosis (MS).

The specific focus of this program is to identify and fund the development of promising new therapies that promote nervous system repair and regeneration in MS. Clene’s lead drug candidate, CNM-Au8®, a catalytically active gold nanocrystal suspension, has been shown to elicit robust remyelination and repair in multiple in vitro and animal models by enhancing energy metabolism in central nervous system cells.

The one-year grant will fund Cohort 2 of REPAIR-MS, a Phase 2 clinical study investigating target engagement of CNM-Au8 in patients with non-active progressive MS. Using non-invasive brain imaging, the study will enroll up to 15 individuals with primary progressive or non-active secondary progressive MS and determine the effects of 12 weeks of CNM-Au8 daily oral dosing on critical brain energy metabolites that have been shown to be compromised in individuals with MS. The study will be carried out at the University of Texas Southwestern Medical School under lead investigator Dr. Peter Sguigna and imaging expert Dr. Jimin Ren. Benjamin Greenberg, M.D., a Professor and Vice Chair of Clinical & Translational Research at UTSW, is not affiliated with this project.

“We are thrilled to be the recipient of a prestigious Fast Forward Grant and eager to advance our understanding of CNM-Au8in the treatment of non-active progressive MS,” said Karen Ho, Ph.D., VP of Translational Medicine, of Clene Nanomedicine. “Our previous REPAIR-PD and REPAIR-MS (Cohort 1) studies demonstrated target engagement with CNM-Au8 treatment in both patients with Parkinson’s Disease and in patients with relapsing remitting multiple sclerosis (RRMS). Positive results from this study will extend the demonstration of brain target engagement of CNM-Au8 to non-active progressive MS as well.”

“There is a significant unmet need for treatments for the progressive loss of function that takes place in all forms of MS,” added Dr. Benjamin Greenberg, Head of Medicine at Clene. “The results from the newly funded study will also build on the results of the randomized, double-blind, placebo-controlled Phase 2 VISIONARY-MS trial in relapsing MS. VISIONARY-MS demonstrated that treatment with CNM-Au8 improves vision and clinical scores across multiple physiological domains as measured by the MS Functional Composite scale, which combines scores for low contrast vision, working memory, fine motor skills, gross motor skills and balance. We embrace the opportunity offered to us by the National MS Society to continue to develop CNM-Au8 as a unique disease-modifying treatment that addresses energetic deficits associated with neurodegeneration.”

"Building on previous work from REPAIR-MS to extend evidence of target engagement for CNM-Au8 exemplifies our effort to provide leverage to de-risk clinical development," said Mark Allegretta, Ph.D., Vice President, Research, National MS Society. "We are eager to see the brain biomarker results from CNM-Au8 treatment in people living with non-active progressive MS from this study".

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.

About the REPAIR Clinical Trial Program
REPAIR-MS and REPAIR-PD are Phase 2 single-center, active-only, sequential group studies examining the brain metabolic effects, safety, pharmacokinetics, and pharmacodynamics of CNM-Au8 in patients who have been diagnosed with MS within 15 years of screening or in patients with PD who have been diagnosed within three years of screening. The objective of these studies is to demonstrate target engagement for CNM-Au8 on CNS biomarkers related to energetics and neuronal membrane stability in patients with MS and PD. Investigators and participants are blinded to dose. Participants,13 patients in REPAIR-PD and 11 patients in REPAIR-MS (all study participants with repeat imaging data), received orally delivered CNM-Au8 daily each morning for 12 weeks. Participants underwent 31P-MRS brain imaging scans to semi-quantitatively measure central nervous system (CNS) energetic metabolites at baseline, prior to administration of drug, and at the end-of-study following at least 12 weeks of exposure to CNM-Au8. The studies are taking place at the University of Texas Southwestern Medical Center with a team of internationally recognized experts in brain imaging and treatment of disorders of the CNS. For more information see ClinicalTrials.gov Identifiers: NCT03993171 and NCT03815916.

About Clene
Clene is a clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative disease by targeting energetic failure, an underlying cause of many neurological diseases. 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 Twitter, LinkedIn and Facebook.

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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