National Institutes of Health Awards $45.1 Million NINDS Grant for CNM-Au8® Study in ALS

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Funding to Support Research and Expanded Access of Investigational Drug in ALS

SALT LAKE CITY, Oct. 05, 2023 (GLOBE NEWSWIRE) -- Clene Inc. (Nasdaq: CLNN), through its wholly owned subsidiary Clene Nanomedicine Inc. in collaboration with Columbia University and Synapticure, has been awarded a four-year grant totaling $45.1 million from the National Institute of Neurological Disorders and Stroke (NINDS), a division of the National Institutes of Health (NIH), to support an Expanded Access Protocol (EAP) for the Company's investigational drug, CNM-Au8 ®, in amyotrophic lateral sclerosis (ALS). An EAP is also referred to as Compassionate Use and is an FDA-regulated pathway that allows people with a serious and life-threatening disease to access an investigational drug that is not yet approved by the U.S. Food and Drug Administration (FDA). In addition to this new EAP, Clene will continue to conduct its currently ongoing ALS EAP programs that have enrolled more than 200 participants since 2019.

The EAP grant is part of the Accelerating Access to Critical Therapies for ALS Act (ACT for ALS). This Act was overwhelmingly supported by Congress and signed into law by President Biden on Dec. 23, 2021, with a call for increased support of public-private partnerships that will innovate the development of, and increase access to, potential new treatments for ALS.

The EAP study will be led by Jinsy A. Andrews, MD, MSc, FAAN, of Columbia University; Eric Anderson, MD, PhD,MBA, FAAN, of Synapticure; and Benjamin Greenberg, MD, MHS, FAAN, Head of Medical of Clene. This EAP will provide eligible people living with ALS to work with their clinician to access CNM-Au8. The EAP is designed to enable the participation of people living with ALS from all 50 states, including remote and rural areas, through Synapticure's telemedicine neurology clinic as well as a network of nationwide clinics. This study will monitor safety, survival and clinical worsening as well as levels of key biomarkers related to disease progression with CNM-Au8 treatment.

"This EAP study will give ALS patients who don't meet the criteria to enroll in a clinical trial an opportunity to try CNM-Au8 as a novel investigational therapy through this EAP program," said Jinsy A. Andrews, M.D., MSc, FAAN, an associate professor of neurology in the Division of Neuromuscular Medicine and director of Neuromuscular Clinical Trials at Columbia University Vagelos College of Physicians and Surgeons. "Programs like this help to advance research and much-needed innovation in ALS."

Dr. Anderson, VP of Clinical Operations and Care Delivery at Synapticure, said: "We are truly excited to be a part of this grant with Clene and Columbia and to support people living with ALS by providing access to treatments that could meaningfully impact the course of their disease. We are grateful to NINDS for recognizing how a virtual platform like Synapticure can provide expanded access programs in a remote capacity. It will allow us to reach people living with ALS across the U.S. who have not previously had access to investigational medicines, like CNM-Au8."

Dr. Greenberg added: "Clene has demonstrated evidence of consistent safety and improved survival for CNM-Au8 across a broad ALS population in two independent Phase 2 trials and an ongoing EAP with up to 3.8 years of follow-up. This new EAP provides access to CNM-Au8 for more people living with ALS and enables the collection of survival, safety and biomarker data in a population not studied in clinical trials. These data can help provide confirmatory support for the existing trial data Clene has gathered in its clinical trials."

This study is supported by NIH grant U01NS136023.

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 Twitter and LinkedIn.

About Synapticure
Synapticure is a neurology specialty telehealth clinic transforming the experience & outcomes of neurodegenerative disease for patients and caregivers. Founded in 2021 by an ALS patient and caregiver, our care model includes quick and easy access to neurologists, behavioral health including psychiatry and therapy, care coordination and additional services into one integrated care experience.

With inclusive insurance coverage including Medicare, we treat patients in all 50 states with ALS, Parkinson's, Huntington's, Alzheimer's and related Dementias. Synapticure partners with health plans, providers, and community organizations to improve the lives of the more than 10 million Americans living with neurodegenerative disease. Learn more at www.synapticure.com.

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.

Media Contact
Ignacio Guerrero-Ros, Ph.D., or David Schull
Russo Partners, LLC
Ignacio.guerrero-ros@russopartnersllc.com
David.schull@russopartnersllc.com
(858) 717-2310

Investor Contact
Kevin Gardner
LifeSci Advisors
kgardner@lifesciadvisors.com
617-283-2856