ALS and MS Clinical Data from Clene's CNM-Au8® Featured in Multiple Presentations at the 2023 American Academy of Neurology Annual Meeting

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SALT LAKE CITY, April 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 diseases, announced that CNM-Au8® results in multiple sclerosis (MS) and amyotrophic lateral sclerosis (ALS) were presented in plenary sessions at the 2023 American Academy of Neurology (AAN) Annual Meeting, currently taking place in Boston. The MS platform presentation and ALS survival poster highlight the results from multiple clinical trials that demonstrated clinical benefit and safety of treatment with CNM-Au8, a cellular energetic nanocatalyst.

A poster presented by James Berry, MD, MPH, from Massachusetts General Hospital and Harvard University, entitled "Evidence for Survival Benefit in ALS with CNM-Au8 Treatment Across Three Study Populations," highlighted the consistent survival results seen across broad ALS populations involving different stages of the disease. These findings support the advancement of clinical development of CNM-Au8 in a confirmatory Phase 3 study. Specific highlights of the poster included:

- Early ALS: Treatment with CNM-Au8 30mg demonstrated a statistically significant survival benefit of 60% and decreased risk of death through 120 weeks versus original placebo randomization.
- Mid-to-late stage ALS: Treatment with CNM-Au8 30mg was associated with a survival benefit of >90% decreased risk of death or permanent assisted ventilation through 24 weeks versus placebo.
- Real world experience ALS: Treatment with CNM-Au8 30mg was associated with median survival of greater than three years in an Expanded Access Program.

In addition, a plenary presentation by Michael Barnett, Ph.D., from the University of Sydney, highlighted results from the VISIONARY-MS study of CNM-Au8 that show improvements in clinical neurologic function and independent quantitative biomarkers of enhanced axonal integrity, measured by visual evoked potential (mf-VEP) amplitude and MRI diffusion tensor imaging (DTI) fractional anisotropy.

The primary and secondary endpoints in the VISIONARY-MS study mITT population demonstrated improved clinical outcomes, independent of an immunomodulatory effect. The prespecified exploratory MRI findings in the VISIONARY-MS study provide evidence of brain neuronal structural integrity assessed by DTI that demonstrated statistically significant results for key metrics of axonal and white matter integrity. Preservation of white matter integrity is associated with decreased cognitive and functional decline in MS patients.

CNM-Au8 was well-tolerated, and no significant safety findings were observed.

Rob Etherington, Clene's President and CEO, said, "With this growing body of evidence, we are increasingly confident that CNM-Au8 has an effect across neurodegenerative diseases, such as ALS and MS, providing a potential treatment option with a novel and complementary mechanism of action for the patient community. Clene now awaits important new biomarker data from both the double-blind and open label periods of the HEALEY ALS Platform Trial. Within the next several months, we will understand the effects of CNM-Au8 on slowed clinical worsening and improved survival beyond the six-month double-blind period, up to 18 months of total treatment in the open-label extension. These data will help determine our regulatory filing strategy. In parallel, Clene plans to meet with the FDA in an end of Phase 2 meeting during the third quarter of 2023 to discuss the regulatory path forward for CNM-Au8 in ALS."

The presentations are now available in the Presentations section of the Clene website.

About CNM-Au8®, a gold nanocrystal suspension
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 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 https://clene.com or follow us on Twitter, LinkedIn, and Facebook.

Forward-Looking Statements

This press release contains "forward-looking statements" which are intended to be covered by the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Clene's actual results may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "might" and "continues," and similar expressions are intended to identify such forward-looking statements. These forward-looking statements involve significant known and unknown risks and uncertainties, many of which are beyond Clene's control and could cause actual results to differ materially and adversely from expected results. Factors that may cause such differences include Clene'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; Clene's ability to achieve commercial success for its marketed products and drug candidates, if approved; Clene's ability to obtain and maintain protection of intellectual property for its technology and drugs; Clene's reliance on third parties to conduct drug development, manufacturing and other services; Clene's limited operating history and its ability to obtain additional funding for operations and to complete the licensing or development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on Clene's clinical development, commercial and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in Clene's Annual Report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in Clene's subsequent filings with the U.S. Securities and Exchange Commission. Clene undertakes no obligation to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based, subject to applicable law. 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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