Clene Reports Positive Topline Results for CNM-Au8® in the Phase 2 VISIONARY-MS Trial in Multiple Sclerosis

August 15, 2022

- ***CNM-Au8 met primary and secondary endpoints of Low Contrast Letter Acuity (LCLA) and modified Multiple Sclerosis Functional Composite (mMSFC) compared to placebo over 48 weeks in the mITT population***
- ***Consistent improvements favoring CNM-Au8 were seen across paraclinical biomarkers, providing physiological evidence for its potential neuroprotective and remyelinating effects***
- ***CNM-Au8 treatment was well-tolerated, and there were no significant safety findings reported***
- ***Results provide support to advance CNM-Au8 into Phase 3 clinical development***
- ***Clene to host a call and webcast at 7:30 am EDT today***

SALT LAKE CITY, Aug. 15, 2022 (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, today announced positive topline results from the Phase 2 VISIONARY-MS trial of CNM-Au8®, an investigational gold nanocrystal suspension, in participants with stable relapsing remitting multiple sclerosis (RRMS).

VISIONARY-MS was a Phase 2 proof-of-concept, multicenter, randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of CNM-Au8 (15 mg or 30 mg daily) as adjunctive therapy to currently available disease-modifying therapies (DMTs) versus placebo over 48 weeks in stable RRMS participants with chronic optic neuropathy.

As announced in February 2022, the trial was stopped prematurely due to COVID-19 pandemic operational challenges, limiting enrollment to 73 out of the 150 planned participants. Due to the limited enrollment, the threshold for significance was pre-specified at p=0.10 prior to database lock. The primary analysis was conducted in a modified intent to treat (mITT) population, which censored invalid data. The mITT population excluded data from a single site (n=9) with LCLA testing execution errors and the timed 25-foot walk data from one subject with a change in mobility assist device. The ITT results were directionally consistent with the mITT results, although the ITT results were not significant.

“These data are very encouraging to us in the MS research and treatment community as we work to address functional improvement in patients,” said Benjamin Greenberg, MD, MHS, FANA, FAAN, CRND Professor of Neurology and one of the trial’s clinical advisors. “The MS community has been successful at limiting relapses, but we need therapies to address progression independent of relapse activity (PIRA). This study was designed as a proof-of-concept evaluation to establish that treatment of neuronal and glial energetic failure can support remyelination and neuroprotection in people living with MS. I am pleased to see the potential effectiveness of CNM-Au8 demonstrated in this trial.”

Primary and secondary results from Baseline to Week 48 were:

- Primary outcome: LCLA letter change in the clinically affected eye (least squares [LS] mean difference, 3.13; 95% CI: -0.08 to 6.33, p = 0.056)
- Secondary outcomes:
  - mMSFC mean standardized change (LS mean difference, 0.28; 95% CI: 0.04 to 0.52, p = 0.0207)
  - mMSFC average rank score (LS mean difference, 13.38; 95% CI: 2.83 to 23.94, p = 0.0138)
  - Time to first repeated clinical improvement to Week 48 (45% vs. 29%, log-rank p=0.3991)

Consistent improvements favoring CNM-Au8 were observed across multiple paraclinical biomarkers, including multifocal visual evoked potentials (mfVEP) amplitude and latency, optical coherence tomography (OCT), and MRI endpoints, including magnetization transfer ratio and diffusion tensor imaging metrics. Placebo treated patients, in contrast, generally worsened as expected across these measures during the 48-week period. These data provide independently assessed quantitative physiological evidence that supports the potential neuroprotective and remyelinating effects of CNM-Au8. The full dataset will be reported at an upcoming scientific congress.

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

Robert Glanzman, MD, FAAN, Clene’s Chief Medical Officer, said, "In this study, CNM-Au8 demonstrated neurological improvements in people with stable relapsing MS as adjunctive therapy to immunomodulatory DMTs. I am very impressed by the consistency of structural and functional improvements demonstrated by CNM-Au8 throughout the neuraxis. With these data, Clene looks forward to initiating a Phase 3 clinical program in people with MS who are experiencing progression independent of relapse activity, the most urgent unmet medical need in MS today. We look forward to the next phase of clinical development.”

Rob Etherington, Clene’s Chief Executive Officer and President, added, “These results further demonstrate the potential of CNM-Au8 to drive neuronal cellular energy production in patients struggling with MS and other neurodegenerative diseases. We also await additional evidence of clinical efficacy from the HEALEY ALS Platform Trial, which is expected to report topline data later in this quarter. Clene will continue to work tirelessly to further CNM-Au8’s development to treat neurodegenerative diseases.”

Conference Call and Webcast Information
Clene will host a conference call and webcast at 7:30 am EDT to discuss the VISIONARY-MS topline results.

Toll free: 1 (888) 770-7152
Conference ID: 5318408
*Press *1 to ask or withdraw a question, or *0 for operator assistance*.

To access the live webcast, please register online at this link. Participants are requested to register at a minimum 15 minutes before the start of the call. A replay of the call will be available two hours after the call and archived on the same web page for six months. A live audio webcast of the call will be available on the Investors section of the Company's website Presentation page . An archived webcast will be available on the Company's website approximately two hours after the event.

About VISIONARY-MS
VISIONARY-MS was a Phase 2 multi-center, randomized, double-blind, placebo-controlled trial to assess the efficacy and safety of CNM-Au8 in participants with stable relapsing remitting multiple sclerosis (RRMS) with a history of chronic visual impairment who are allowed disease-modifying therapy (DMT). Enrolled subjects were randomized 1:1:1 to CNM-Au8 15 mg/day, 30 mg/day, or placebo. As announced in February 2022, the trial was stopped prematurely due to COVID-19 pandemic operational challenges, enrolling 73 out of the 150 planned participants. Due to limited enrollment, the threshold for significance was pre-specified at p=0.10 prior to database lock. The primary endpoint was the change in best corrected-low contrast letter acuity (BC-LCLA) from baseline to week 48 in the clinically affected eye. Key secondary efficacy outcomes assessed neurological function by the modified MS Functional Composite (mMSFC) including 25-Foot Timed Walk, Symbol Digit Modalities Test, 9-Hole Peg Test (dominant and non-dominant hands), and LCLA (affected and fellow eye) from baseline through Week 48. For more information, see ClinicalTrials.gov. Identifier: NCT03536559. The open label extension of VISIONARY-MS is ongoing.

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 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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