



## Clene Nanomedicine's RESCUE-ALS Phase 2 Results Selected for Late-Breaking Presentation at 32nd International Symposium on ALS/MND

December 7, 2021

- Late-breaker oral presentation by Professor Steve Vucic, University of Sydney Medical School and Northcott Chair of Neurology
- *CNM-Au8<sup>®</sup> demonstrated significantly slowed disease progression: decreased risk of 6-point ALSFRS-R decline, and improved quality of life in early ALS patients in the RESCUE-ALS trial*
- CNM-Au8<sup>®</sup> was well tolerated and safe with no serious adverse events or drug discontinuations

SALT LAKE CITY, Dec. 07, 2021 (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, announced the [32nd International Symposium on ALS/MND](#), a Motor Neurone Disease (MND) Association event, has selected Clene's Phase 2 RESCUE-ALS clinical trial results of CNM-Au8<sup>®</sup>, a gold nanocrystal suspension, in the treatment of amyotrophic lateral sclerosis (ALS) for a late-breaking oral presentation as well as a poster presentation.

### Late-Breaking Presentation

**Title:** RESCUE-ALS: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of CNM-Au8 to Slow Disease Progression in Amyotrophic Lateral Sclerosis

**Presenter:** Professor Steve Vucic, University of Sydney Medical School and Northcott Chair of Neurology

**Session Details:** Session 10: Closing Session – Late Breaking News

**Time:** Friday, Dec. 10, 2021, at 13:05 ET

### Poster Presentation

**Title:** RESCUE-ALS Trial: a Phase 2, Randomized, Double-Blind, Placebo Controlled Study of CNM-Au8 to Slow Disease Progression in Amyotrophic Lateral Sclerosis

**Presenter:** Dr. Robert Glanzman, MD FAAN, Chief Medical Officer of Clene

**Session Details:** Live Poster Session A, CLT-14

**Time:** Tuesday, Dec. 7, 2021, from 11:50-13:20 ET

The poster abstract is published in [Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration Journal](#) and will be accessible during the Conference to registered attendees throughout the conference. A live poster session will be presented during the above designated time where attendees can chat live with the presenter. The poster slides can be accessed through Clene's website at: <https://invest.clene.com/overview/default.aspx>.

With over 1,000 delegates, the International Symposium is the largest medical and scientific conference specific to MND/ALS and is the premier event in MND research for discussion on the latest advances in research and clinical management. This year's virtual symposium will take place on December 7 - 10, 2021.

### About RESCUE-ALS

RESCUE-ALS, a Phase 2 multi-center, randomized, double-blind, parallel-group, placebo-controlled trial examined the efficacy, safety, pharmacokinetics and pharmacodynamics of CNM-Au8 in patients with early amyotrophic lateral sclerosis (ALS). In the trial, 45 subjects were randomized 1:1 to receive either active treatment with CNM-Au8 (30 mg) or placebo in addition to their current standard of care over a 36-week treatment period. The objective of the trial was to assess the impact of CNM-Au8 on disease progression in patients with early-stage ALS through changes in motor unit index (MUNIX). MUNIX values were evaluated for four muscles in the hand, arm, and leg: the abductor digit minimi, abductor pollicis brevis, tibialis anterior and biceps brachii from baseline through 36 weeks of treatment. While the trial did not meet the primary endpoint, change in MUNIX score at week 36, results suggest protection of lower motor neurons in limb onset ALS, which accounts for approximately 70% of the ALS population, and showed benefit for both limb and bulbar patients across the clinical endpoints. In this study, there were statistically significant improvements in clinically relevant exploratory endpoints through week 36, including reducing the risk of ALS disease progression and improving quality of life. In addition, RESCUE-ALS showed evidence for a potential long-term survival benefit from CNM-Au8. CNM-Au8 was selected by FightMND of Australia, and Clene was provided a substantial grant to investigate efficacy in ALS utilizing novel neurophysiological endpoints including MUNIX at two clinical sites in Australia. For more information, please see [ClinicalTrials.gov](#) Identifier: [NCT04098406](#).

### About CNM-Au8<sup>®</sup>, a gold nanocrystal suspension

Clene's lead drug candidate, CNM-Au8, a catalytically active gold nanotherapeutic, is the result of a patented manufacturing breakthrough. The catalytically active nanocrystals of CNM-Au8 drive critical cellular energy producing reactions in the brain that enable neuroprotection and remyelination by increasing neuronal and glial resilience to disease-relevant stressors. CNM-Au8 crosses the blood-brain barrier and is not associated with the toxicities related to synthetic gold compounds or nanoparticles manufactured via alternative methods. CNM-Au8 is being evaluated in a Phase 3 registration trial for the treatment of amyotrophic lateral sclerosis (ALS). In the REPAIR Program Phase 2 open-label biomarker clinical trials, CNM-Au8 demonstrated target engagement in the treatment of Parkinson's disease (PD) and multiple sclerosis (MS). REPAIR-PD has concluded, and REPAIR-MS will continue with the initiation of a second MS dosing cohort. Preclinical data, both published in peer-reviewed journals and presented at scientific congresses, demonstrate that treatment of neuronal cultures with CNM-Au8 improves survival of neurons, protects neurite networks, decreases intracellular levels of reactive oxygen species and improves mitochondrial capacity in response to cellular stresses induced by numerous disease-relevant neurotoxins. Oral treatment with CNM-Au8 improved functional behaviors in rodent models of ALS, MS and PD versus vehicle

(placebo). CNM-Au8<sup>®</sup> 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 with first-in-class nanotherapeutics to treat energetic failure, an underlying cause of many neurological diseases. Our lead drug candidate, CNM-Au8, is an oral suspension of gold nanocrystals that drive critical cellular energetic metabolism in the central nervous system (CNS). CNM-Au8 increases energy production and utilization to accelerate neurorepair and improve neuroprotection. CNM-Au8 is currently being evaluated in a Phase 3 registration trial in amyotrophic lateral sclerosis (ALS) and a Phase 2 trial for the treatment of chronic optic neuropathy in patients with stable relapsing multiple sclerosis (MS). Clene has also advanced into the clinic an aqueous solution of ionic zinc and silver for anti-viral and anti-microbial uses. 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](http://www.clene.com) or follow us on Twitter, LinkedIn and Facebook.

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