Clene Nanomedicine, Inc. Completes Enrollment in Rescue-ALS Clinical Trial for Treatment of Amyotrophic Lateral Sclerosis (ALS) with Lead Nanocatalytic Therapeutic, CNM-Au8

SALT LAKE CITY, September 8, 2020 - Clene Nanomedicine, Inc., ("Clene") a clinical-stage biopharmaceutical company and its Australian subsidiary, Clene Australia Pty Ltd., today announced the completion of patient enrollment in its RESCUE-ALS Phase 2 study. The multi-center study is designed to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of CNM-Au8 in early symptomatic ALS patients. The objective of this study is to demonstrate improvements in muscle function using a sophisticated electromyography technique called Motor Unit Number Index (MUNIX), which quantitatively reflects loss or preservation of motor neurons in ALS. The trial is substantially funded by a grant from FightMND.

"Completion of enrollment is ahead of schedule, clearly demonstrating the unmet medical need in this devastating disease. In multiple preclinical models of ALS, CNM-Au8 has been shown to promote motor neuron health, reduce neuron loss, and preserve motor neuron function. We believe the unique mechanisms of CNM-Au8 provide the potential to be an effective disease-modifying therapy for patients with ALS," said Robert Glanzman, MD, FAAN, Chief Medical Officer of Clene.

"Completing enrollment is a major milestone in our Phase 2 RESCUE-ALS trial. We are looking forward to unveiling the data expected in the summer of 2021. This key milestone could provide proof-of-concept for a novel nanotherapeutic agent for the treatment of ALS, and represents important advances for Clene," said Rob Etherington, President and CEO of Clene.

About RESCUE-ALS

RESCUE-ALS is a Phase 2 multi-center randomized, double-blind, parallel group, placebo-controlled study examining the efficacy, safety, pharmacokinetics, and pharmacodynamics of CNM-Au8 in participants who are newly symptomatic with ALS (within 24-months of screening or 12-months from diagnosis). Enrolled subjects will be randomized 1:1 to receive either active treatment with CNM-Au8 30mg or placebo in addition to their current standard of care. Participants will receive their randomized treatment over 36 consecutive weeks during the Treatment Period. The objective of this study is to assess the impact of improving neuronal bioenergetics, reducing reactive oxygen species, and promoting protein homeostasis with CNM-Au8 to slow disease progression in patients with ALS.

About CNM-Au8

CNM-Au8 is a concentrated, aqueous suspension of clean-surfaced faceted gold nanocrystals (Au) that are believed to act catalytically to support important intracellular biological reactions. CNM-Au8 consists solely of nanoparticles of gold organized into faceted, geometrical crystals held in suspension in sodium bicarbonate buffered, pharmaceutical grade water. CNM-Au8 has demonstrated safety in Phase 1 studies in healthy volunteers and has shown both remyelination and neuroprotection effects in multiple preclinical models. Preclinical data, both published in peer-reviewed journals and presented at scientific congresses demonstrate that treatment with CNM-Au8 in neuronal cultures improves survival of neurons, protects neurite networks, decreases intracellular levels of reactive oxygen species, and improves mitochondrial capacity in response to cellular stress, induced by multiple disease-relevant neurotoxins. Oral treatment with CNM-Au8 improved functional behaviors in rodent models of ALS, multiple sclerosis, and Parkinson's disease versus vehicle (placebo). CNM-Au8 is currently being tested in a Phase 2 clinical study for the treatment of chronic optic neuropathy in patients with multiple sclerosis in addition to Phase 2 and Phase 3 clinical studies for disease progression in patients with amyotrophic lateral sclerosis (ALS). Two target-engagement studies are also ongoing utilizing 7-Tesla

^{31}Phosphorous Magnetic Resonance Spectroscopy, evaluating improvement in bioenergetics in the brains of patients with MS and Parkinson's disease (PD).

About Amyotrophic Lateral Sclerosis (ALS)
ALS is a universally fatal neurodegenerative neurodegenerative disorder that results in loss of motor neurons in the cerebral cortex, brain stem, and spinal cord. ALS, also known as Lou Gehrig's disease, leads to the death of the neurons controlling voluntary muscles resulting in weakness, muscle atrophy, and progressive paralysis. ALS affects more than 15,000 patients in the United States and is the most prevalent adult-onset progressive motor neuron disease.

About Clene
Clene Nanomedicine, Inc. is a privately-held, clinical-stage biopharmaceutical company focused on the development of unique therapeutics for neurodegenerative diseases. Clene has innovated a novel nanotechnology drug platform for the development of a new class of orally-administered neurotherapeutic drugs. Clene has also advanced into the clinic, an aqueous solution of ionic zinc and silver for anti-viral and anti-microbial uses. Founded in 2013, the company is based in Salt Lake City, Utah with R&D and manufacturing operations located in North East, Maryland. For more information, please visit www.clene.com.

About FightMND
FightMND is a not-for-profit registered charity, founded in 2014. It was established to raise the awareness of Motor Neurone Disease (MND) in Australia, to increase funding for research to find an effective treatment and cure and to provide care equipment for MND patients. We have a clear objective – to a have a world free from MND. FightMND is Australia's largest independent MND foundation focused on funding large- scale, collaborative research and clinical trials. The generous donations contributed by everyday Australians, right across the country, has enabled FightMND to raise and commit millions to cure and care initiatives.

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