Clene Nanomedicine Announces Over 50% of Subjects Randomized in RESCUE-ALS Clinical Trial for Treatment of Amyotrophic Lateral Sclerosis (ALS) with Lead Nanocatalytic Therapeutic, CNM-Au8

SALT LAKE CITY, May 26, 2020 – Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company, today announced its Australian subsidiary has completed over 50% of participant randomization in the Phase 2 RESCUE-ALS study with its lead nanocatalytic therapy, CNM-Au8, for the treatment of Amyotrophic Lateral Sclerosis (ALS). The RESCUE-ALS study is substantially funded by FightMND.

The randomized, double-blind, multi-center RESCUE-ALS study is an ongoing study evaluating the efficacy, safety, pharmacokinetics, and pharmacodynamics of CNM-Au8 in early symptomatic ALS patients. The study has to date enrolled 26 subjects of 42 planned participants.

"Enrollment in this Phase 2 study is ahead of schedule and clearly emphasizes the unmet medical need in this devasting disease. In preclinical models of ALS, CNM-Au8 has been shown to promote neuroprotection and reduce neurodegeneration. We believe the unique mechanism of CNM-Au8 provides the potential to be an effective disease-modifying therapy for patients with ALS and we look forward to completing enrollment," said Robert Glanzman, MD, FAAN, Chief Medical Officer of Clene.

"We are excited to achieve this enrollment milestone for our Phase 2 RESCUE-ALS trial and believe we are on track to complete full enrollment in the third quarter of this year," said Rob Etherington, President and CEO of Clene.

About RESCUE-ALS

RESCUE-ALS is 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 ALS (within 24-months of screening or 12-months from diagnosis) and with a clinically probable or possible or definite ALS diagnosis. Enrolled subjects will be randomized 1:1 to receive either active treatment with CNM-Au8 30 mg or placebo in addition to their current standard of care. Participants will receive their randomized oral treatment daily over 36 consecutive weeks during the Treatment Period. The treatment is taken by mouth once daily first thing every morning. The objective of this study is to assess bioenergetic catalysis 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 nanocrystalline gold (Au) that acts catalytically to support important intracellular biological reactions. CNM-Au8 consists solely of gold atoms 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 both remyelination and neuroprotection effects in multiple preclinical models. Preclinical data presented at scientific congresses demonstrated that treatment with CNM-Au8 in neuronal cultures improved survival of neurons, protected neurite

networks, decreased intracellular levels of reactive oxygen species, and improved mitochondrial capacity in response to cellular stress, induced by multiple disease-relevant neurotoxins. Oral treatment with CNM-Au8 improved functional behaviors in a rodent models of ALS, multiple sclerosis, and Parkinson's disease versus vehicle (placebo). CNM-Au8 has received regulatory approval to proceed to clinical studies for the treatment of remyelination failure in patients with multiple sclerosis and neuroprotection in patients with amyotrophic lateral sclerosis (ALS) and Parkinson's disease.

About Amyotrophic Lateral Sclerosis (ALS)

ALS is a universally fatal 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. 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.

Investor Contact

Kaitlyn Brosco
The Ruth Group
646-536-7032
kbrosco@theruthgroup.com

Media Contact

Kirsten Thomas
The Ruth Group
508-280-6592
kthomas@theruthgroup.com