

Clene Nanomedicine Announces First Patient Dosed in the RESCUE-ALS Clinical Trial for the Treatment of Amyotrophic Lateral Sclerosis (ALS) with Lead Nanocatalytic Therapeutic, CNM-Au8

SALT LAKE CITY, January 21, 2019 – Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company, today announced its Australian subsidiary had completed enrollment and dosing of the first participant 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 objective of the randomized, double-blind RESCUE-ALS study is to demonstrate that improvements in brain bioenergetic cellular support in early symptomatic ALS patients treated with CNM-Au8 will help preserve motor neurons survival and function. The primary endpoint is the mean change in the average difference between active treatment and placebo from baseline through week 36 for the Motor Unit Number Index (MUNIX) score, which quantitatively reflects the loss of motor neurons in ALS—the primary cause of clinical progression in ALS,” said Robert Glanzman, MD, FAAN, Clene’s Chief Medical Officer.

“We are excited to advance CNM-Au8 clinically into this Phase 2 study for ALS patients,” said Rob Etherington, President and CEO of Clene. “As neurodegenerative diseases such as ALS have very few treatment options, this study will prove whether CNM-Au8 may be an effective disease-modifying treatment for people with ALS.”

“We are very excited to partner with Clene on the Phase 2 study in ALS, RESCUE-ALS,” said Professor Steve Vucic, Director of Neurophysiology, Department of Neurology, at Sydney Medical School, Westmead Hospital. “CNM-Au8 offers an innovative approach of potentially treating neurodegenerative diseases, such as ALS, for which there are no effective treatments at present. We are hopeful that CNM-Au8 will be an effective therapy in the future and this trial will go a long way in addressing this question.”

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 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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