Clene Nanomedicine Publishes Results Demonstrating Preclinical Efficacy of CNM-Au8 Gold Nanocrystals for Remyelination in Multiple Sclerosis in *Scientific Reports*

Preclinical models demonstrate robust remyelinating activity, functional myelin generation, and improved motor function

Researchers conclude CNM-Au8 represents a novel remyelinating therapeutic for MS

SALT LAKE CITY, February 11, 2020 – Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company, today announced the publication of original research in *Scientific Reports* of the Nature Publishing Group in the article, "Nanocatalytic activity of clean-surfaced, faceted nanocrystalline gold enhances remyelination in animal models of multiple sclerosis." The published data describe the preclinical efficacy of CNM-Au8 to support remyelinating activity, functional myelin generation, and improved motor function in animal models of Multiple Sclerosis (MS).

Robert Glanzman, MD FAAN, Chief Medical Officer of Clene Nanomedicine, commented, "We are gratified at the publication of these data. These results establish the rationale for our ongoing Phase 2 clinical trial, VISIONARY-MS, which is designed to demonstrate the efficacy of CNM-Au8 for the treatment of chronic optic neuropathy in patients with non-active relapsing MS."

Key results from published study include:

- CNM-Au8 treatment of oligodendrocyte precursor cells in culture resulted in oligodendrocyte maturation and expression of myelin differentiation markers.
- In response to CNM-Au8, co-cultured central nervous system cells exhibited elevated levels of the redox coenzyme nicotine adenine dinucleotide (NAD+), elevated total intracellular ATP levels, and elevated extracellular lactate levels, along with upregulation of myelin-synthesis related genes, collectively resulting in functional myelin generation.
- Oral delivery of CNM-Au8 improved motor functions of cuprizone-treated mice in both open field and kinematic gait studies.
- CNM-Au8, a suspension of clean-surfaced, faceted gold nanocrystals, represents a novel remyelinating therapeutic for MS.

"This publication demonstrates that CNM-Au8 (clean-surfaced, faceted gold nanocrystals) are capable of actively catalyzing cellular reactions necessary for therapeutic remyelination. These results further validate our entirely new approach using therapeutic gold nanocatalysts as a mechanism to support the cellular viability and enhanced function of neurons and oligodendrocytes. CNM-Au8 is one of a limited number of drugs being developed which have demonstrated remyelination capabilities. We believe these data exemplify a strong step forward in the development of a treatment to improve function in the lives of more than one million people living with MS in the U.S.," said Karen Ho, PhD, Director of Translational Medicine and the corresponding author.

Reference

Robinson, et al. “Nanocatalytic activity of clean-surfaced, faceted nanocrystalline gold enhances remyelination in animal models of multiple sclerosis.” Scientific Reports, Nature Publishing Group. Online at www.nature.com/articles/s41598-020-58709-w

About CNM-Au8

CNM-Au8 is a concentrated, aqueous suspension of clean-surfaced, faceted nanocrystalline gold (Au) that acts catalytically to support important intracellular energetic 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 rodent models of ALS, multiple sclerosis, and Parkinson’s disease versus vehicle (placebo). CNM-Au8 has received regulatory approvals in the US, Canada and Australia, and is currently in six, Phase 2 clinical studies for the treatment of patients with non-active, relapsing multiple sclerosis, amyotrophic lateral sclerosis (ALS), and Parkinson’s disease.

About Multiple Sclerosis (MS)

MS is an inflammatory, demyelinating disease of the central nervous system and is the most common (non-traumatic) cause of neurological disability in young adults. The most common clinical presentation, relapsing MS (RMS), is characterized by sub-acute attacks of neurological disability, ranging from loss of vision to numbness and tingling, walking difficulty, dizziness, and/or paralysis. Most people with RMS are diagnosed between the ages of 20 and 40, with three times more women being affected than men. A recent study led by the National MS Society estimates that nearly 1 million people are living with MS in the United States. Despite currently-available disease-modifying therapies, approximately 30% of people with MS have developed a non-active, progressive form of the disease, for which there are no approved, effective therapies, leading to significant loss of quality of life. There remains an urgent need for therapies that promote repair, neuroprotection and remyelination for all people with MS.

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.

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