

## **Clene Nanomedicine Awarded Research Grant from the National Multiple Sclerosis Society to Support Clinical Development of its Lead Nanocatalytic Therapeutic, CNM-Au8**

**SALT LAKE CITY, October 14, 2019 --**

Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company, today announced that the National Multiple Sclerosis Society (NMSS) has awarded the company a research grant totaling more than \$339,000 to support the clinical development of its nanocatalytic therapeutic, CNM-Au8, for the treatment of multiple sclerosis (MS).

“We are very pleased to have been awarded a Fast Forward research grant from the National Multiple Sclerosis Society for the development of CNM-Au8, the lead asset in our clean-surfaced gold nanocrystal therapeutic pipeline. We believe the unique mechanism of CNM-Au8 to improve cellular bioenergetics represents a promising new approach for the treatment of MS as a remyelinating agent,” said Rob Etherington, President and CEO of Clene. “CNM-Au8 may help improve myelin integrity and restore function of patients with MS – outcomes presently being investigated in the ongoing VISIONARY-MS Phase 2 study.”

The National MS Society created the Fast Forward program to support commercial and academic organizations engaged in the development of new therapies and diagnostic tools for MS. Fast Forward is designed to bridge the preclinical commercial funding gap by targeting funds to de-risk therapeutic development of novel clinical programs. The Fast Forward grant will support pharmacodynamic studies to determine the effects of CNM-Au8 on various biological markers from patients in the VISIONARY-MS remyelination Phase 2 study.

“There is a critical unmet need for multiple sclerosis therapies that can promote the repair of myelin and protect the nervous system from further damage,” said Mark Allegretta, PhD, Vice President of Research at the National MS Society. “We’re pleased to provide funding to advance our understanding of biomarkers related to lipid metabolism, bioenergetics and oxidative stress, not only as potential indicators of target engagement for CNM-Au8, but also to expand the biomarker repertoire available to the MS field.”

### *About VISIONARY-MS*

The objective of the VISIONARY-MS trial is to assess the efficacy and safety of CNM-Au8 as a remyelinating treatment for vision-impairing MS lesions in participants who have chronic vision impairment. The primary endpoint is the improvement in remyelination measured by improvement in low contrast vision after 24 weeks of treatment. The secondary endpoint is

improvement in visual evoked potentials, or the speed of communication between the eye and visual cortex, after 24 weeks of treatment. Participants drink a 2 oz. dose of the nanocrystal suspension daily each morning. Results of the study are expected by early 2021.

#### *About CNM-Au8*

CNM-Au8 is a concentrated, aqueous suspension of clean surfaced faceted nanocrystalline gold (Au) that acts catalytically to support various 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 studies. Preclinical studies of CNM-Au8 demonstrated that the drug protects motor neurons from death through a novel nanocatalytic mechanism, increasing the body's ability to resist several stressors associated with this disease. CNM-Au8 has received regulatory approval to proceed to clinical studies for the treatment of multiple sclerosis remyelination failure and neuroprotection of amyotrophic lateral sclerosis (ALS) and Parkinson's disease.

#### *About Multiple Sclerosis*

Multiple sclerosis is an unpredictable, often disabling disease of the central nervous system that disrupts the flow of information within the brain, and between the brain and body. Symptoms vary from person to person and range from numbness and tingling, to walking difficulties, fatigue, dizziness, pain, depression, blindness and paralysis. The progress, severity and specific symptoms of MS in any one person cannot yet be predicted, but advances in research and treatment are leading to better understanding and moving us closer to a world free of MS. Most people with MS are diagnosed between the ages of 20 and 50, with three times more women than men being diagnosed with the disease. A recent study led by the National MS Society estimates that nearly 1 million people are living with MS in the United States; twice as many than previously thought.

#### *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](http://www.clene.com).

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