

Clene Nanomedicine, Inc. Announces Selection of CNM-Au8 for the Harvard Led HEALEY ALS Platform Trial, a Clinical Trial for Amyotrophic Lateral Sclerosis

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Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company, announced today that the Sean M. Healey & AMG Center for ALS at Mass General has selected CNM-Au8 for inclusion in the first ever Platform Trial for the treatment of amyotrophic lateral sclerosis (ALS).

The Healey Center issued a call earlier this year for the best therapeutic candidates to apply for entry into the HEALEY ALS Platform Trial. They received responses from nearly 30 applicants across ten countries. Members from the Healey Center Science Advisory Committee, a group of renowned ALS scientists, chose the top five therapeutic candidates, including Clene's lead clinical asset, CNM-Au8. The selection of CNM-Au8 into the Healey ALS Platform Trial includes substantial financial support and provides access to over 50 expert ALS clinical trial sites across the United States.

“Our goal,” said Merit Cudkowicz, MD, MSc, Director of the Healey Center, “is to lower the barriers for our pharma and academic colleagues to bring their exciting therapies for ALS forward to clinical trials. We are determined to accelerate therapy development for ALS.”

Important preclinical work supporting the effort with CNM-Au8 was performed in the laboratory of Nicholas J. Maragakis, Director of the ALS Center for Cell Therapy and Regeneration Research at Johns Hopkins, using human induced pluripotent stem cells from ALS patients. Dr. Maragakis is Chair of Clene's Scientific Advisory Board for ALS.

Dr. Jonathan Glass, Professor of Neurology and Pathology at Emory University School of Medicine, as well as Director of the Emory ALS Center, remarked, “CNM-Au8 is quite an interesting compound that is ready for testing in ALS clinical trials. Its inclusion in the Platform Trial initiative is an excellent way to move forward for the development of CNM-Au8 as a potential therapeutic for ALS.”

“We are very pleased Clene's CNM-Au8 has been selected for participation in the Healey ALS Platform Trial. We believe the unique mechanism of CNM-Au8 represents a promising new approach for the treatment of neurodegenerative diseases, including ALS, with the potential for meaningful impact for the community of people diagnosed with this devastating and debilitating disease,” said Rob Etherington, President and CEO of Clene. “We are continuing the development of CNM-Au8 in several clinical studies set to launch later this year.”

About ALS

ALS is a fatal neurodegenerative disorder of motor neurons of 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 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 CNM-Au8

CNM-Au8 is a concentrated, aqueous suspension of pure 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 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 ALS and Parkinson's disease.

About Clene

Clene Nanomedicine, Inc. (www.clene.com) is a privately held clinical-stage biopharmaceutical company, based in Salt Lake City, Utah with R&D and manufacturing operations located in North East, Maryland. Clene has innovated a novel nanotechnology drug platform for the development of a new class of orally-administered neurotherapeutic drugs. Clene was founded in 2013.