

Clene Nanomedicine Announces First Patients Enrolled in HEALEY ALS Platform Trial

SALT LAKE CITY, August 3rd, 2020 – Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company, is very pleased that the Sean M Healey & AMG Center for ALS at Mass General announced the first patients have been enrolled into the HEALEY ALS Platform Trial being conducted at sites of the Northeast ALS (NEALS) consortium.

Clene Nanomedicine’s lead drug candidate, CNM-Au8, is a first-of-its-kind therapeutic nanocatalyst with demonstrated neuroprotective and remyelinating properties in preclinical models. CNM-Au8 was selected as one of the first drug regimens to be evaluated as an ALS treatment in the HEALEY ALS Platform Trial by a panel of expert amyotrophic lateral sclerosis (ALS) scientists. This breakthrough trial, the first ever platform trial for the treatment of ALS, is designed to reduce trial time, reduce costs and increase patient participation in developing novel therapies for ALS. The trial includes substantial financial support from philanthropic donors and foundations, and provides access to 54 expert ALS clinical trial sites across the United States from the NEALS consortium.

“We are excited that the HEALEY ALS Platform Trial has begun enrollment of patients, and that the dosing of CNM-Au8, as one of the first three therapies chosen, will begin imminently,” said Rob Etherington, President and CEO of Clene. “This trial will be key in our mission of finding solutions to the progressive neurologic impairment of ALS, in order to aid those suffering from this deadly neurodegenerative disease.”

Robert Glanzman, MD, FAAN, Clene's Chief Medical Officer, further commented, “We at Clene are very excited to be partnering with the Healey Center for ALS at Mass General in this critically important effort. The announcement of first patients enrolled is the culmination of a lot of hard work by a large collaborative team, led by the Healey Center.”

“This is a huge milestone for the ALS community and beyond, and the team here at the Healey Center is eager and excited to begin enrolling patients in the first-ever platform trial for this disease,” says Merit Cudkowicz, MD, director of the Sean M. Healey & AMG Center for ALS and chief of Neurology at MGH. “We’re grateful to our supporters and collaborators who have worked tirelessly throughout this pandemic to ensure the trial can begin safely and efficiently.”

For more information on the trial, please visit [MassGeneral HEALEY ALS Platform Trial](https://www.massgeneral.org/HEALEYALSPlatformTrial) or [ClinicalTrials.gov NCT04297683](https://clinicaltrials.gov/ct2/show/study/NCT04297683).

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 rodent models of ALS, multiple sclerosis, and Parkinson's disease versus vehicle (placebo). CNM-Au8 has received regulatory approval to initiate Phase 2 and 3 clinical studies for neuroprotection and remyelination in patients with multiple sclerosis, 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 (aka 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.

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