SALT LAKE CITY, July 30, 2019
Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company developing a new class of orally-administered neurotherapeutic drugs using a novel drug development platform, announced today that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to CNM-Au8, the Company's therapeutic nanocatalyst for the treatment of amyotrophic lateral sclerosis (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 leading to progressive paralysis. ALS affects more than 15,000 patients in the United States. CNM-Au8 is being studied in a Phase 2 clinical trial, called REPAIR-ALS, in adults with ALS.

REPAIR-ALS is a single-center open label pilot, sequential group, investigator and patient blinded study to assess the CNS metabolic effects, safety, pharmacokinetics, and pharmacodynamics of CNM-Au8 in patients who have been diagnosed with ALS within twelve months of study entry. The primary endpoint is the ratio of the oxidized to reduced form of nicotinamide adenine dinucleotide (NAD+:NADH) measured non-invasively by ^{31}phosphorous magnetic resonance spectroscopy. The REPAIR-ALS study is being conducted at the UT Southwestern Medical Center by the principal investigator, Dr. Jeffrey Elliott.

"ALS is a debilitating condition with few available therapies, and patients lack treatment options," said Rob Etherington, President and CEO at Clene. "We are pleased with the continued progress of CNM-Au8 in this ongoing clinical trial, and we anticipate presenting additional data from the study in the second half of 2020."

The FDA grants orphan designation to promote the development of promising products for rare conditions affecting fewer than 200,000 U.S. patients annually. It qualifies a company for certain financial benefits, including seven years of market exclusivity following marketing approval, tax credits for clinical research costs, eligibility for Orphan Product grants and the waiver of certain administrative fees.

Through the process of nanocatalysis, CNM-Au8 has demonstrated remyelination effects as a potential treatment for Multiple Sclerosis, and as a neuroprotective agent for ALS, Parkinson's disease, and other neurodegenerative disorders.

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 crystals of various faceted, geometrical shapes 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 *in vitro* and *in vivo* models. CNM-Au8 has received regulatory approval to proceed to Phase 2 clinical

studies for the treatment of multiple sclerosis remyelination 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 was founded in 2013.