

***Clene Nanomedicine, Inc. Awarded \$1.37M AUD Grant from FightMND to Conduct Phase 2 Clinical Study for the Treatment of Amyotrophic Lateral Sclerosis***

*Salt Lake City, UT, 16 September 2019*

Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company, announced today its Australian subsidiary has been awarded a \$1.37 M AUD grant from the FightMND (Fight Motor Neuron Disease) foundation of Australia. The grant will substantially fund a clinical trial to assess the efficacy and safety of Clene's novel nanocatalyst, CNM-Au8, to slow disease progression in patients with amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's Disease.

ALS is the most prevalent adult-onset progressive motor neuron disease. It is a fatal neurodegenerative disorder affecting motor neurons of the cerebral cortex, brain stem, and spinal cord. ALS leads to the death of the neurons controlling voluntary muscles resulting in progressive paralysis. CNM-Au8 is the first of new class of medicines that act via unique catalytic mechanisms to both support bioenergetic cellular reactions and eliminate harmful by-products of cellular metabolism, which contribute to degeneration of motor neurons in ALS.

The FightMND grant will fund the Phase 2 clinical trial, RESCUE-ALS. This randomized, double-blind, placebo-controlled study will be conducted at two clinical sites in Sydney, Australia: Westmead Hospital MND Clinic and the Sydney Brain Mind Centre under the guidance of expert ALS clinicians, Drs. Steve Vucic and Matthew Kiernan. "The nanocatalyst exerts unique effects on human motor neurons. We are excited by its potential therapeutic benefits in ALS," stated Dr. Vucic. "This is a really excellent opportunity to develop a new therapeutic approach to ALS," Dr. Kiernan added.

Rob Etherington, President and CEO of Clene, added, "We are delighted to receive this award, which will allow us to further develop our clean-surfaced, faceted gold nanocrystal therapeutic, CNM-Au8, for the treatment of ALS. With few truly disease-modifying options available for neurodegenerative diseases like ALS, Clene is striving to develop innovative new treatments, for we realize the urgency of patients who daily fight this devastating disease. We would like to express our gratitude to FightMND and all of its contributors for helping to accelerate our efforts to make a safe and effective treatment available to ALS patients."

*About CNM-Au8*

CNM-Au8 is a concentrated, aqueous suspension of faceted clean surfaced 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 in preclinical studies. CNM-Au8 has received regulatory approval to proceed to clinical studies for the treatment of multiple sclerosis, ALS, and Parkinson's disease.

### *About Clene*

Clene Nanomedicine, Inc. ([www.clene.com](http://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.

### *About FightMND*

FightMND is a not-for-profit registered charity, founded in 2014. It was established to raise the awareness of Motor Neurone Disease (MND) in Australia, to increase funding for research to find an effective treatment and cure and to provide care equipment for MND patients. We have a clear objective – to have a world free from MND.

FightMND is Australia's largest independent MND foundation focused on funding large-scale, collaborative research and clinical trials. The generous donations contributed by everyday Australians, right across the country, has enabled FightMND to raise and commit millions to cure and care initiatives.