Clene Nanomedicine Presents Updated Blinded Interim Data from the VISIONARY-MS Phase 2 Study

Presentation today during Joint ACTRIMS-ECTRIMS Meeting at MSVirtual2020

Data indicate a continued positive safety profile and the potential to improve MS visual and functional endpoints

SALT LAKE CITY, September 11, 2020 - Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company, today announced the presentation of expanded interim results from the VISIONARY-MS Phase 2 study in stable relapsing multiple sclerosis (RMS) patients with chronic visual impairment. VISIONARY-MS is an ongoing study investigating CNM-Au8, a bioenergetic nanocatalyst under investigation for neuro-reparative and remyelination capabilities. Blinded data were analyzed from all trial participants (combined placebo, low-dose, and high-dose CNM-Au8 treated patients), which demonstrated clinically relevant median improvements across the overall RMS study population in accepted MS functional scales, including low contrast vision. The data will be available starting September 11 at 8:00 a.m. ET as an on-demand e-Poster at the MSVirtual2020: 8th Joint ACTRIMS-ECTRIMS (Americas Committee for Treatment and Research in MS – European Committee for Treatment and Research in MS Meeting), held online September 11-13 (www.msvirtual2020.org).

VISIONARY-MS is a double-blind, randomized, placebo-controlled Phase 2 trial evaluating the efficacy and safety of CNM-Au8 as a remyelinating and neuro-reparative treatment in people who have stable relapsing MS with visual impairment. Enrolled participants must have chronic optic neuropathy, defined as visual impairment with no episodes of acute optic neuritis within the six months prior to enrollment, and non-active disease (i.e., be "clinically stable"), defined as no MS relapses within the prior three months. Concomitant immunomodulatory disease-modifying (DMT) MS therapies are allowed with over 90% of patients receiving approved DMTs as background standard of care. Participants are randomized to low-dose CNM-Au8, high-dose CNM-Au8, or placebo. The primary endpoint is improvement in low contrast letter acuity (LCLA) from baseline to week 24, however, all participants will remain in the double-blind, placebo-controlled treatment period through week 48, until the last participant completes week 24.

The presentation (P0243) titled "VISIONARY-MS: A Phase 2 Clinical Trial of Catalytic Gold Nanocrystals, CNM-Au8, for the Treatment of Chronic Optic Neuropathy" features interim blinded efficacy results from the first 44 enrolled participants on treatment for up to 36 weeks. Through week 36, patients on treatment (active CNM-Au8 or placebo) demonstrated notable median improvements in LCLA (n = 21, 42 eyes), as well as the three remaining modified Multiple Sclerosis Functional Composite (MSFC) sub-scales, including Symbol Digit Modalities Test (cognition), 9-Hole Peg Test (upper extremity function), and Timed 25-foot Walk (gait). The available safety data indicate that CNM-Au8 is well-tolerated with most adverse events characterized as mild in severity. No serious adverse events related to study drug have been reported to date. Interim data from the first 34 enrolled patients was previously presented during the Joint NAIMS-MSVISUAL Symposium at the ACTRIMS Forum in February 2020.

"We believe these blinded data, which build upon our ACTRIMS presentation earlier in the year, provide evidence for consistent and relevant clinical improvements across recognized MS functional endpoints on top of current standard of care. This presentation reiterates the progress we hope to achieve in

addressing the urgent unmet needs of promoting remyelination and neurorepair for patients with MS," said Robert Glanzman, MD, FAAN, Chief Medical Officer of Clene.

"We are thrilled to present this important efficacy and safety data at a prominent and international MS conference. We will continue to strive to demonstrate the clinical potential of CNM-Au8 and our patented Clean-Surfaced Nanocrystal therapeutics for the treatment of debilitating neurodegenerative diseases," said Rob Etherington, President and CEO of Clene.

About VISIONARY-MS

The objective of the VISIONARY-MS (Treatment of Visual Pathway Deficits In Chronic Optic Neuropathy for Assessment of Remyelination in Stable RMS) trial is to assess the efficacy and safety of CNM-Au8 as a neuroprotective and remyelinating treatment for people with stable relapsing MS who have chronic vision impairment. The primary endpoint is improvement in low contrast letter acuity from Baseline to Week-24. Key secondary endpoints include improvements from Baseline to Week-24 in the remaining modified-Multiple Sclerosis Functional Composite subscales (Symbol Digit Modalities Test, 9-Hole Peg Test and Timed 25-Foot Walk). Participants drink a 2 oz. (60 ml) dose of the nanocrystal suspension (or placebo) daily each morning. Full, unblinded results of the study are anticipated near the end of 2021.

About CNM-Au8

CNM-Au8 is a concentrated, aqueous suspension of clean-surfaced faceted gold nanocrystals that act catalytically to support important intracellular biological reactions. CNM-Au8 consists solely of nanoparticles of gold, composed of clean-surfaced, 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 has shown both remyelination and neuroprotection effects in multiple preclinical (animal) models. Preclinical data, both published in peer-reviewed journals and presented at scientific congresses, demonstrate that treatment of neuronal cultures with CNM-Au8 improves survival of neurons, protects neurite networks, decreases intracellular levels of reactive oxygen species, and improves mitochondrial capacity in response to cellular stresses 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 is currently being tested in a Phase 2 clinical study for the treatment of chronic optic neuropathy in patients with multiple sclerosis in addition to Phase 2 and Phase 3 clinical studies for disease progression in patients with amyotrophic lateral sclerosis (ALS).

About Multiple Sclerosis (MS)

MS is an inflammatory, demyelinating disease of the central nervous system and is the most common (non-traumatic) cause of neurological disability in young adults. The most common clinical presentation, relapsing MS (RMS), is characterized by sub-acute attacks of neurological disability, ranging from loss of vision to numbness and tingling, walking difficulty, dizziness, and/or paralysis. Most people with RMS are diagnosed between the ages of 20 and 40, with three times more women being affected than men. A recent study led by the National MS Society estimates that nearly 1 million people are living with MS in the United States. Despite currently available disease-modifying therapies, approximately 30% of people with MS have developed a non-active, progressive form of the disease, for which there are no approved, effective therapies, leading to significant loss of quality of life. There remains an urgent need for therapies that promote repair, neuroprotection and remyelination for all people with MS.

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. Clene has also advanced into the clinic an aqueous solution of ionic zinc and silver for anti-viral and anti-microbial uses. 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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