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

Presentation today during Joint NAIMS-IMSVISUAL Symposium at ACTRIMS Forum 2020

Results demonstrate well-tolerated safety profile and notable preliminary trends of improved low-contrast vision in addition to improvement in standard MS functional endpoints

SALT LAKE CITY, February 27, 2020 – Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company, today announced interim blinded data from the VISIONARY-MS Phase 2 study demonstrating median improvements in functional scores in the enrolled population of patients with relapsing multiple sclerosis (MS). The interim results will be featured in an oral presentation today at the Joint NAIMS-IMSVISUAL Symposium in conjunction with the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2020, held February 27-29 in West Palm Beach, Florida, as well as during a poster presentation during ACTRIMS.

VISIONARY-MS is an ongoing double-blind, randomized, placebo-controlled Phase 2 trial evaluating the efficacy and safety of CNM-Au8 as a remyelinating and neuroprotective treatment in people who have 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, defined as no MS relapses within the prior three months. Concomitant immunomodulatory disease modifying MS therapies are allowed. 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 remain in the double-blind, placebo-controlled treatment period through week 48, until the last participant completes week 24. The study is presently being conducted across eight clinical sites in Australia with multiple sites in North America soon opening enrollment.

Interim blinded efficacy results, up to week 36, from the first 34 enrolled participants demonstrate notable median improvements in LCLA and 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). 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. The most frequently reported adverse events include headache, upper respiratory infection, and sore throat. The full unblinded results from the study are anticipated mid-2021.

“These preliminary results are encouraging as we progress to achieve the critical unmet therapeutic goals of remyelination and neuroprotection for patients with multiple sclerosis,” said Robert Glanzman, MD, Clene’s Chief Medical Officer. “These data add to the growing body of clinical evidence demonstrating that CNM-Au8, a suspension of catalytic, clean-surfaced, faceted gold nanocrystals, has the unique ability to improve remyelination and provide axonal neuroprotection. The consistent median improvements observed across the MSFC functional

domains in the population of participants in VISIONARY-MS are exciting. We are gratified to share the details of the study and these early efficacy data with the MS community at one of the most prominent conferences committed to research and treatment for this devasting disease."

The details of the presentations:

VISIONARY-MS Study: Phase 2 Design Rationale, Baseline Data, and Interim Blinded Results

- **Joint NAIMS-IMSVISUAL Symposium, Part 2**
  - Presenter: Robert Glanzman, MD, Chief Medical Officer, Clene Nanomedicine
  - Time: Thursday, February 27 from 1:20 – 1:35 p.m. ET
  - Location: Palm Beach County Convention Center, Grand Ballroom
- **Poster: Session 1 (P079)**
  - Presenter: Robert Glanzman, MD, Chief Medical Officer, Clene Nanomedicine
  - Time: Thursday, February 27 from 6:00 – 8:00 p.m. ET
  - Location: Exhibit Hall A at the Palm Beach County Convention Center

About VISIONARY-MS

The objective of the VISIONARY-MS (Treatment of **V**isual Pathway Deficits **I**n Chronic **O**ptic **N**europathy for **A**ssessment of **R**em**y**elination in Stable R**MS**) trial is to assess the efficacy and safety of CNM-Au8 as a neuroprotective and remyelinating treatment for people with 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 reduction in latency (the speed of communication between the eye and visual cortex), as measured by visual evoked potentials, after 24 weeks of treatment. Participants drink a 2 oz. dose of the nanocrystal suspension (or placebo) daily each morning. Results of the study are expected by mid 2021.

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 proceed to clinical studies for the treatment of remyelination failure in patients with multiple sclerosis and neuroprotection in patients with amyotrophic lateral sclerosis (ALS) and Parkinson's disease.

About Multiple Sclerosis

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. 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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