

**Clene Nanomedicine to Present Data at the 34th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS 2018)
Demonstrating Activation of Myelination Gene Transcription in Oligodendrocytes by a Gold Nanocrystal Therapeutic, CNM-Au8**

- A poster presentation will describe bioenergetic enhancement of remyelination in oligodendrocytes by Clene Nanomedicine's lead clean-surfaced, faceted gold nanocrystal asset, CNM-Au8, as a potential new treatment for multiple sclerosis at ECTRIMS in Berlin, Oct 10-12, 2018
- Clene's Phase II VISIONARY-MS trial of CNM-Au8 for the treatment of chronic optic neuropathy associated with relapsing remitting multiple sclerosis commences this month

Berlin, Oct 10, 2018 -- Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company, is leveraging the potent biocatalytic properties of clean-surfaced, faceted gold nanocrystals grown using a proprietary electro-crystal-chemistry method to develop a new class of Clean Surface Nanotherapeutic (CSNTM) drugs. The lead asset, CNM-Au8, possesses several promising characteristics as a therapeutic modality, including: an oral delivery route; clean toxicology results from 6-month rodent and 9-month canine studies; blood brain barrier penetrance; and a clean safety and tolerability profile in a first-in-human study involving 80 healthy human volunteers.

Today, in a poster presentation at the meeting of the 34th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), Clene's Head of Translational Medicine, Karen Ho, PhD, will present results obtained in collaboration with lead author Damiano Fantini, PhD and Professor Stephen D. Miller's lab at the Northwestern University Feinberg School of Medicine demonstrating that treatment of oligodendrocyte precursor cells with CNM-Au8 stimulates the cells to express mRNA transcripts consistent with the cells' program of differentiation and myelination. Key genes involved in oligodendrocyte maturation were upregulated at least 2-fold by CNM-Au8.

The myelin sheath surrounding axons aids in the rapid conduction of electrical impulses, an activity essential for higher order function in vertebrate animals including humans. Myelin is comprised of 70% lipids and is uniquely produced by oligodendrocytes in the brain. An intriguing observation made by the group was that transcripts encoding genes for lipid metabolism were also highly up-regulated with

CNM-Au8 treatment. Similar treatment with a positive control (triiodothyronine), which also differentiates oligodendrocytes *in vitro*, did not demonstrate lipid transcript upregulation. The direct stimulation of a myelin-producing transcriptional program by CNM-Au8 has important implications for its utility as a potential treatment for multiple sclerosis (MS). MS is a neurodegenerative disease caused by demyelination of neurons and which affects 2.3 million people world-wide.

The novel advantages of Clene's innovative gold nanocrystal growing methodology underscores the significant potential these nanocrystals hold to address unmet medical needs. In work presented at a national multiple sclerosis meeting earlier this year (ACTRIMS 2018), Michael Hotchkin, Chief Business Officer of Clene Nanomedicine, presented preclinical data demonstrating the robust remyelinating effects of CNM-Au8 in *in vitro* and *in vivo* demyelination models of multiple sclerosis. Data was also presented demonstrating the ability of CNM-Au8 to restore motor functions and behaviors to mice treated with the demyelinating toxin, cuprizone.

"With CNM-Au8, we are disrupting the old paradigms of drug discovery and presenting the pharmaceutical field with revolutionary new therapeutics that break down the boundaries of classical receptor-based pharmacology. Discovering how to consistently grow biologically catalytically active, clean-surfaced nanocrystals from a variety of different metals, their alloys, and compounds means we can now make a portfolio of safe, cost-effective, and mechanistically novel new drugs. Based on the strength of our preclinical data, we are very optimistic about the therapeutic potential of CNM-Au8 in helping patients with demyelinating and other neurodegenerative disorders," said Glen Frick MD, PhD, Chief Medical Officer of Clene.

Stephen Miller, Judy Guggenheim Research Professor of Microbiology-Immunology and Professor of Microbiology-Immunology and Dermatology at Northwestern University concluded, "I am very excited about these results as there are no drugs currently in use that stimulate myelin repair. This is a huge unmet need for the treatment of the devastating consequences of MS."

"We are excited about our VISIONARY-MS Phase 2 clinical trial in Multiple Sclerosis patients, now underway and recruiting patients. The trial is designed to determine CNM-Au8's remyelination efficacy in a disease desperately in need of remyelination therapies," rejoined CEO Rob Etherington.

About Clene Nanomedicine

Clene Nanomedicine, Inc., (www.CleneNanomedicine.com), is a privately held clinical-stage biopharmaceutical company, based in Salt Lake City, UT with technical R&D and manufacturing in North East, MD. Clene was founded in December 2013.

Clene's platform technology develops catalytically active metallic nanocrystals with oral availability. The nanocrystals are created by patent-protected technology that capitalizes on techniques from plasma physics, hydro electro-crystallization, and materials science. Clene's first asset is CNM-Au8. Its second asset, CNM-G-AgZn17, is being readied to commence a Phase 1/2a anti-viral clinical study by 2019.

About CNM-Au8

CNM-Au8 is being developed for remyelination of CNS disorders. CNM-Au8 is a novel oral gold nanocrystal suspension, which has demonstrated remyelination across multiple animal models of demyelination.

Clene will commence a Phase 2 Study to treat Chronic Visual Pathway Deficits (Optic Nerve or Optic Radiation Lesions) in patients with stable Relapsing-Remitting Multiple Sclerosis (RRMS) in 2018 to prove the remyelinating effects of CNM-Au8. RRMS is characterized as a demyelinating condition resulting in damage to the myelin sheath protective covering surrounding nerve fibers in the brain and spinal cord, with consequential loss of function. No therapy is currently approved in any global market for the remyelination of multiple sclerosis lesions.

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