Clene Nanomedicine Receives Patent Notice of Allowance in the United States for using Gold Nanocrystals for the Treatment of Multiple Sclerosis

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- ***Resulting patent to cover methods of using Clene's lead candidate CNM-Au8, now in Phase 2 and 3 trials for Multiple Sclerosis (MS) and Amyotrophic lateral sclerosis (ALS)***
- ***Latest patent allowance adds to Clene's robust IP estate including over 130 patents issued and pending applications***

SALT LAKE CITY, Jan. 19, 2021 (GLOBE NEWSWIRE) -- Clene Inc. (NASDAQ: CLNN) (along with its subsidiaries, "Clene") today announced that its wholly-owned subsidiary Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company, was issued a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for its invention for using its patented clean-surfaced gold nanocrystals for treating patients with multiple sclerosis (MS).

Clene notes that its previously patented gold nanocrystals have surfaces that are substantially free from organic impurities and are therefore "clean" relative to surfaces of gold nanoparticles made by other processes. The allowed application discloses that these gold nanocrystals can be suspended in water and can be taken orally, for example, by a person with MS.

"As the leading developer of clean surfaced nanocrystal therapeutics for humans, we continue to expand our patent estate and are pleased to receive this latest Notice of Allowance from the USPTO. While the only approved treatments for MS today are immunomodulators, we see an opportunity to treat MS through a completely different mechanism of action utilizing the therapeutic bioenergetic effects of catalytic gold nanocrystals, such as CNM-Au8. This Notice of Allowance comes as we are conducting two Phase 2 studies of our lead drug candidate CNM-Au8 in the treatment of MS," stated Rob Etherington, President and CEO of Clene.

MS affects an estimated 1 million people in the U.S. and 2.5 million worldwide, with a treatment market valued at $23 billion globally.

New data is expected from Clene's REPAIR-MS Phase 2 study of CNM-Au8 in the second half of 2021. Prior interim results from this study showed CNM-Au8 was associated with improvements across key central nervous system (CNS) bioenergetic metabolites.

Clene's VISIONARY-MS Phase 2 study is evaluating the efficacy and safety of CNM-Au8 as a remyelinating and neuro-reparative treatment in stable relapsing MS patients with chronic visual impairment. Interim data from the Phase 2 VISIONARY-MS trial demonstrated notable, exposure-related median improvements in the primary endpoint. Completion of enrollment is expected by the end of 2021.

Clene's worldwide patent portfolio in the new field of clean-surfaced nanocrystal therapeutics includes over 100 patents issued and allowed, with around 30 more pending. The issued patents cover state of matter claims for suspensions and solutions, as well as processes for making the materials, devices for conducting the unique electro-crystal chemistry processes, and methods of using the novel materials, such as in this instance of using clean-surfaced gold nanocrystals for treating patients with MS.

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 gold nanoparticles, 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 neuroprotective 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, MS 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 MS, in addition to Phase 2 and Phase 3 clinical studies for disease progression in patients with ALS.

About Clene

Clene is a 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.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Clene's actual results may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "might" and "continues," and similar expressions are intended to identify such forward-looking statements. These forward-looking statements involve significant known and unknown risks and uncertainties, many of which are beyond Clene's control and could cause actual results to differ materially and adversely from expected results. Factors that may cause such differences include Clene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and

marketing approval; Clene's ability to achieve commercial success for its marketed products and drug candidates, if approved; Clene's ability to obtain and maintain protection of intellectual property for its technology and drugs; Clene's reliance on third parties to conduct drug development, manufacturing and other services; Clene's limited operating history and its ability to obtain additional funding for operations and to complete the licensing or development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on Clene's clinical development, commercial and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in Clene's recently filed registration statement on Form S-4, as well as discussions of potential risks, uncertainties, and other important factors in Clene's subsequent filings with the U.S. Securities and Exchange Commission. Clene undertakes no obligation to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based, subject to applicable law. All information in this press release is as of the date of this press release. The information contained in any website referenced herein is not, and shall not be deemed to be, part of or incorporated into this press release.

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