# Clene Nanomedicine Receives Two Patent Notice of Allowances in the U.S. for Its Platform Nanocrystal Therapeutic Technology

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IP portfolio now totals over 160 patents issued, allowed, and pending

SALT LAKE CITY, April 30, 2021 (GLOBE NEWSWIRE) -- Clene Inc. (NASDAQ: CLNN) (along with its subsidiaries, “Clene”) and its wholly owned subsidiary Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company dedicated to revolutionizing the treatment of neurodegenerative disease using bioenergetic nanocatalysis, today announced the U.S. Patent and Trademark Office has issued Notices of Allowance for two important patent applications covering device and process claims for its platform technology and advanced stage clean-surfaced nanocrystal therapeutic candidates.

The first allowed application titled “Continuous Methods for Treating Liquids and Manufacturing Certain Constituents (e.g., Nanoparticles) in Liquids, Apparatuses and Nanoparticles and Nanoparticle/Liquid Solution(s) Resulting Therefrom” covers a broad set of device claims pertaining to Clene’s platform electrochemical technology for making solutions and suspensions.

Additionally, very broad process claims for forming nanocrystals (such as gold), in liquids, is covered in the second allowed application titled “Continuous, Semicontinuous and Batch Methods for Treating Liquids and Manufacturing Certain Constituents (e.g., Nanoparticles) in Liquids, Apparatuses and Nanoparticles and Nanoparticle/Liquid Solution(s) and Colloids Resulting Therefrom.”

Both patents, once issued, will continue to provide important intellectual property protection for CNM-Au8, Clene’s lead drug candidate. CNM-Au8 is now being evaluated across seven clinical studies for the treatment of amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS), and Parkinson’s disease including a Phase 3 registration trial in ALS for which results are expected in the first half of 2022.

“Our leadership position in clean-surfaced nanocrystal therapeutics is fortified by our growing patent estate. These IP assets become increasingly valuable as our clinical pipeline advances, and as CNM-Au8 nears completion of its pivotal Phase 3 trial and potential commercialization,” stated Rob Etherington, President and CEO of Clene.

Clene’s worldwide patent portfolio in the new field of clean-surfaced nanocrystal therapeutics now includes over 130 patents issued and allowed, with around 30 more applications 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.

**About CNM-Au8**

Clene’s lead drug candidate, CNM-Au8, a bioenergetic nanocatalyst, is a stable, aqueous suspension of catalytically active gold (Au) nanocrystals. In a patented breakthrough, clean surfaced nanocrystalline CNM-Au8 drives critical cellular bioenergetic reactions in the brain to increase cellular energy, accelerate neurorepair, and improve neuroprotection. CNM-Au8 crosses the blood-brain barrier and is not associated with the toxicities related to synthetic gold compounds or nanoparticles manufactured via synthetic chemistry. CNM-Au8 is currently being evaluated in a Phase 3 registration trial in amyotrophic lateral sclerosis (ALS), a Phase 2 trial examining disease progression via a novel electromyography technique in patients with early ALS, a Phase 2 trial for the treatment of chronic optic neuropathy in patients with stable relapsing multiple sclerosis (MS), and Phase 2 brain target engagement studies in patients with Parkinson’s disease (PD) and MS. 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 PD versus vehicle (placebo).

**About Clene**

Clene, a clinical-stage biopharmaceutical company focused on neurodegenerative disease, is leading the way by using nanotechnology to treat bioenergetic failure, which underlies many neurological diseases. Clene has innovated a novel nanotherapeutic platform to create a new class of drugs—bioenergetic nanocatalysts. Clene’s lead drug candidate, CNM-Au8, is a concentrated nanocrystalline gold (Au) suspension that drives critical cellular bioenergetic reactions in the CNS. CNM-Au8 increases cellular energy to accelerate neurorepair and improve neuroprotection. Currently, CNM-Au8 is being investigated for efficacy and safety in a Phase 3 registration trial for ALS and in Phase 2 trials for multiple sclerosis and Parkinson’s disease. Clene has also advanced into the clinic an aqueous solution of ionic zinc and silver for anti-viral and anti-microbial uses. The company is based in Salt Lake City, Utah with R&D and manufacturing operations in 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 Annual Report filed on Form 10K, 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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