Clene Nanomedicine Reports Topline Results of Phase 2 COVID-19 Study of CNM-ZnAg

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- *Primary endpoint of time to substantial symptom resolution was not met in acutely symptomatic, non-hospitalized COVID-19 patients*
- *CNM-ZnAg treatment was safe and well-tolerated*

SALT LAKE CITY, Dec. 27, 2022 (GLOBE NEWSWIRE) -- Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, “Clene”) and its wholly owned subsidiary Clene Nanomedicine Inc., a clinical-stage biopharmaceutical company today announced topline study results from its Phase 2 investigational trial with CNM-ZnAg, an ionic solution of zinc and silver, for the treatment of non-hospitalized acutely symptomatic participants infected with COVID-19.

The Phase 2 multicenter, randomized, double-blind, placebo-controlled trial assessed the efficacy and safety of CNM-ZnAg in COVID-19 infected participants in Brazil. Study participants were randomized 1:1:2 to receive daily low dose CNM-ZnAg, high dose CNM-ZnAg, or placebo in addition to standard supportive care for up to 21 days. The primary endpoint assessed the time to substantial alleviation of COVID-19 symptoms through 28 days, confirmed over a continuous period ≥ 48 hours, in the modified intent-to-treat (mITT) population (all participants with PCR documented SARS-CoV-2 infection, n=288). No clinical benefit was observed versus placebo. CNM-ZnAg was safe and well-tolerated, and no safety signals were identified.

Rob Etherington, Clene’s CEO, commented, “While COVID has not been a therapeutic focus of the company, we were compelled to explore the potential of CNM-ZnAg to help address the global pandemic. At this time, we will cease further development for COVID. We are heartened by the safety profile of CNM-ZnAg, the second asset developed through our technology platform, and its future potential in other antiviral and antibacterial areas. We continue our focus on treatment of neurodegenerative diseases with our lead asset, CNM-Au8, which is advancing towards registrational trials.”

About CNM-ZnAg, a zinc and silver nanocrystal suspension
Clene’s drug candidate, CNM-ZnAg, an ionic solution of zinc and silver, is the result of a patented manufacturing process. CNM-ZnAg has broad spectrum antiviral and antibacterial activity in multiple disease models.

About Clene
Clene is a clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative disease by targeting energetic failure, an underlying cause of many neurological diseases. 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 or follow us on Twitter, LinkedIn and Facebook.

Forward-Looking Statements
This press release contains “forward-looking statements” within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, which are intended to be covered by the “safe harbor” provisions created by those laws. Clene’s forward-looking statements include, but are not limited to, statements regarding our or our management team’s expectations, hopes, beliefs, intentions or strategies regarding our future operations. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “will,” “would,” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements represent our views as of the date of this press release and involve a number of judgments, risks and uncertainties. We anticipate that subsequent events and developments will cause our views to change. We undertake no obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ include our ability to demonstrate the efficacy and safety of our drug candidates; the clinical results for our 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; our ability to achieve commercial success for our drug candidates, if approved; uncertainty regarding whether potential strategic partnerships will result in any agreements or transactions, or, if completed, any agreements or transactions will be successful or on attractive terms; our limited operating history and our ability to obtain additional funding for operations and to complete the development and commercialization of our drug candidates; and other risks and uncertainties set forth in “Risk Factors” in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this press release, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to rely unduly upon these statements. 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.

Media Contact
Ignacio Guerrero-Ros, Ph.D. or David Schull
Russo Partners, LLC
Ignacio.guerrero-ros@russopartnersllc.com
David.schull@russopartnersllc.com
(858) 717-2310

Investor Contact
Kevin Gardner
LifeSci Advisors
kgardner@lifesciadvisors.com
617-283-2856