Clene and APST Enter Into an Agreement to Support FDA's Recommendation for Long-Term NfL Biomarker Analyses of CNM-Au8®'s Impact on NfL Reduction

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- *Longitudinal ALS patient data from APST Research will enable a more robust analysis of the effect of CNM-Au8 on NfL biomarkers*
- *APST Research data includes thousands of people living with ALS including clinical, survival, and longitudinal NfL data*
- *Clene plans to analyze the APST ALS NfL biomarker and clinical dataset to compare NfL change from its ongoing NIH-sponsored EAP to address the FDA's request for supportive evidence of CNM-Au8's effect on NfL reduction observed in the HEALEY ALS Platform Trial*
- *Clene plans to submit a New Drug Application (NDA) in second-half 2025*

SALT LAKE CITY, Feb. 25, 2025 (GLOBE NEWSWIRE) -- Clene Inc. (Nasdaq: CLNN) (along with its subsidiaries, "Clene") and its wholly owned subsidiary Clene Nanomedicine Inc., a late clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS), today announced that it has entered into an agreement with German-based APST Research GmbH (APST) to utilize its extensive NfL database to support the FDA-recommended analyses of CNM-Au8®'s effect on NfL decline in participants in ongoing Expanded Access Protocols (EAPs).

APST maintains one of the largest comprehensive ALS repositories of people living with ALS, including demographic data, clinical data, ALS motor phenotypes and biomarker data, specifically, serum neurofilament light chain (sNfL). The database in the repository comprises extensive sNfL data from over 4,300 ALS patients as well as self-reported ALSFRS-R. The APST platform offers digitized data on thousands of individuals living with ALS to comprehensively view the disease's progression by gathering information on ALS phenotypes, biomarker data, and patient-reported outcomes. This effort utilized cutting-edge data collection and analytics to provide a comprehensive long-term natural history of NfL change. Comparisons to the APST NfL dataset will be a crucial element of the FDA-recommended statistical analysis plan for NfL evaluations of NIH-sponsored EAP participants.

The NfL dataset being analyzed by Clene includes data from more than 1625 ALS patients, aligning the biomarker data of NfL to clinical ALSFRS-R assessments, slow vital capacity (SVC), and clinical events such as ventilation support and nutrition intervention. The objective of the planned analyses is to compare NfL change observed in the NIH-sponsored EAP participants to matched controls using the APST dataset, and to demonstrate that the rate of NfL change is associated with survival in people living with ALS.

Clene has supported the treatment of nearly 500 people living with ALS through its three (3) ALS EAP programs to collect Real-World Evidence (RWE) of the effects of CNM-Au8 in ALS. RWE evidence collected from EAP participants may be supportive of the observed survival improvement and NfL decline observed in the HEALEY ALS Platform Trial with CNM-Au8 30 mg treatment. Clene plans to submit the statistical analysis plan for the NIH-sponsored EAP NfL analyses to the FDA shortly. Analyses of NIH-sponsored EAP NfL reduction, if positive, will support the planned NDA submission for potential Accelerated Approval of CNM-Au8 in ALS, planned in the second half of 2025.

Across over 800 participant years of treatment with CNM-Au8, no significant safety concerns or safety trends have been identified. No serious adverse events (SAEs) have been identified as related to CNM-Au8 treatment by any investigator to date.

"We are excited to enter into this endeavor with one of the world's largest ALS NfL datasets in order to supplement available biomarker NfL data from our NIH-sponsored EAP, and to support the existing clinical study data for the potential review of an application for approval of CNM-Au8 in ALS via an accelerated regulatory pathway," said Clene's CEO, Rob Etherington. "We remain dedicated to the ALS community and are honored to continue our efforts to help critically ill patients and their families."

"Our extensive and robust data collection empowers pharmaceutical companies to advance their clinical research and trials, driving us toward a deeper understanding of ALS disease progression" said APST's founder and CEO, Thomas Meyer, a renowned ALS key opinion leader.

About Clene
Clene Inc., (Nasdaq: CLNN) (along with its subsidiaries, "Clene") and its wholly owned subsidiary Clene Nanomedicine Inc., is a late clinical-stage biopharmaceutical company focused on improving mitochondrial health and protecting neuronal function to treat neurodegenerative diseases, including amyotrophic lateral sclerosis, Parkinson's disease, and multiple sclerosis. CNM-Au8 ® is an investigational first-in-class therapy that improves central nervous system cells' survival and function via a mechanism that targets mitochondrial function and the NAD pathway while reducing oxidative stress. CNM-Au8® is a federally registered trademark of Clene Nanomedicine, Inc. 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 X (formerly Twitter) and LinkedIn.

About APST Research
APST is a digital research platform and service provider for clinical research in ALS. Collaborating with leading ALS centers in Germany and Europe, the APST platform generates clinical, phenotypic and biomarker data, patient-reported outcomes and real-world experiences of innovative medicines and technologies in ALS. APST's mobile "ALS App" directly connects people with ALS, providing trusted ways of generating patient-centric data.

APST is on a mission to meet the needs of pharmaceutical companies pioneering urgently needed ALS medicines with high-quality patient data and clinical knowledge.

For more information on how APST's ALS repository supports ALS clinical research, visit https://apstresearch.com/en/ or follow us on LinkedIn.

About CNM-Au8®

CNM-Au8 is an oral suspension of gold nanocrystals developed to restore neuronal health and function by increasing energy production and utilization. The catalytically active nanocrystals of CNM-Au8 drive critical cellular energy producing reactions that enable neuroprotection and remyelination by increasing neuronal and glial resilience to disease-relevant stressors. CNM-Au8® is a federally registered trademark of Clene Nanomedicine Inc.

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 Clene's expectations regarding the availability of an accelerated approval regulatory pathway, the timing of clinical trials and the submission of an NDA, Clene's intention to follow the FDA's recommendation to provide data from the ongoing EAPs and address the FDA's requests, and that Clene can provide the additional evidence to meet the FDA's data requests. In addition, any statements that refer to 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. Some factors that could cause actual results to differ include general market conditions; whether clinical trials of our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities, or do not otherwise produce positive results, which may cause us to incur additional costs or experience delays in completing, or ultimately be unable to complete; 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 drug candidates, if approved; Clene's limited operating history and its ability to obtain additional funding for operations and to complete the development and commercialization of its 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.

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