Spectral AI Begins Enrollment in Pivotal Study to Validate DeepView AI® for Burn Injuries

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DALLAS, Jan. 11, 2024 (GLOBE NEWSWIRE) -- **Spectral AI, Inc. (NASD:MDAI) ("Spectral AI" or the "Company")**, an artificial intelligence (AI) company focused on medical diagnostics for faster and more accurate treatment decisions in clinical wound care, announces the enrollment of the first patient in the pivotal study to validate DeepView AI® using its proprietary imaging technology for burn size and healing assessment. This pivotal study is expected to be the final clinical trial before seeking FDA marketing authorization for the burn indication in 2025 and will be conducted in burn centers and emergency departments across the US, enrolling both adults and pediatric patients.

Niko Pagoulatos, Ph.D., Chief Operating Officer of the Company stated: "We believe this study will further demonstrate the truly innovative and versatile nature of our technology, as well as its ability to predict burn wound healing potential on the first day of injury with significantly greater accuracy and speed than the methods currently used today. We continue to utilize $251 million of non-dilutive government funding since 2019 to validate DeepView for burn indication, while aggressively advancing other clinical indications like diabetic foot ulcers in pursuit of our 'one platform —multiple clinical indications' strategy."

"We are excited to begin enrollment in this pivotal study implementing the DeepView system in clinical sites across the United States. The study will help us validate DeepView's game-changing AI to accurately assess burn wound healing potential on day-one which could lead to early treatment decisions," said Jeffrey C. Carter, MD, FACS, the lead investigator for the study. "This study is anticipated to deepen the knowledge and understanding of how DeepView will transform burn care pathways while improving patient outcomes, concurrently strengthening our country against the challenges of Burn Mass Casualty Incidents to safeguard and prepare for unforeseen emergencies."

The data obtained in the study will be compared to assessment by physicians and used for regulatory submission to the FDA by the first half of 2025. Further details of the study can be found at clinicaltrials.gov.

This project is being supported in whole or in part with federal funds from the Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under contract number 75A50123C00049. The findings and conclusions have not been formally disseminated by HHS and should not be construed to represent any agency determination or policy.

About Spectral AI

Spectral AI, Inc. is a Dallas-based predictive AI company focused on medical diagnostics for faster and more accurate treatment decisions in wound care, with initial applications involving patients with burns and diabetic foot ulcers. The Company is working to revolutionize the management of wound care by "Seeing the Unknown®" with its DeepView system. DeepView is a predictive diagnostic device that offers clinicians an objective and immediate assessment of a wound's healing potential prior to treatment or other medical intervention. With algorithm-driven results and a goal of substantially exceeding the current standard of care in the future, DeepView is expected to provide faster and more accurate treatment insight towards value care by improving patient outcomes and reducing healthcare costs. For more information about DeepView, visit www.spectral-ai.com.

Forward Looking Statements

Certain statements made in this release are "forward looking statements" within the meaning of the "safe harbor" provisions of the United States Private Securities Litigation Reform Act of 1995, including statements regarding the Company's strategy, plans, objectives, initiatives and financial outlook. When used in this press release, the words "estimates," "projected," "expects," "anticipates," "forecasts," "plans," "intends," "believes," "seeks," "may," "will," "should," "future," "propose" and variations of these words or similar expressions (or the negative versions of such words or expressions) are intended to identify forward-looking statements.

These forward-looking statements are not guarantees of future performance, conditions or results, and involve a number of known and unknown risks, uncertainties, assumptions and other important factors, many of which are outside Company's control, that could cause actual results or outcomes to differ materially from those discussed in the forward-looking statements. As such, readers are cautioned not to place undue reliance on any forward-looking statements.

Investors should carefully consider the foregoing factors and the other risks and uncertainties described in the "Risk Factors" sections of the Company's filings with the SEC, including the Registration Statement and the other documents filed by the Company. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements.

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