

Spectral Al Achieves 100% Pediatric Enrollment in Burn Centers for Pivotal U.S. Burn Study

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DALLAS, July 02, 2024 (GLOBE NEWSWIRE) -- Spectral AI, Inc. (Nasdaq: MDAI) ("Spectral AI" or the "Company"), an artificial intelligence (AI) company focused on medical diagnostics for faster and more accurate treatment decisions in wound care, today announced that it has achieved 100% pediatric patient enrollment at burn centers for its 2024 pivotal study designed to validate the AI-driven algorithm used by its DeepView™ System for its burn indication.

This pivotal study is scheduled to be completed in the fourth quarter of 2024 and is the final clinical trial before the Company seeks FDA approval of its DeepView™ System for burn indication in 2025.

"Due to the investigators' enthusiasm and the potential to change burn care, we have met pediatric enrollment goals for burn centers at an unprecedented 6 months," said Jeffrey E. Carter, MD, FACS, Lead Investigator. "We are continuing to enroll adult patients and pediatric patients through emergency departments to enrich and validate the DeepView algorithm."

"We are grateful to our team for their continuing hard work and dedication in advancing this important clinical trial," said Peter M. Carlson, CEO of Spectral Al. "Burn wounds can be devastating, especially for children who are particularly vulnerable to these injuries. Empowering clinicians to deliver an immediate, accurate assessment of pediatric burn wounds is of critical importance. We believe that the DeepView™ System, powered by our propriety Al-driven algorithm, has the potential to change the standard of burn care by supporting early treatment decisions that can lead to improved patient outcomes."

Spectral Al's DeepView System utilizes proprietary multispectral imaging, trained and tested against a proprietary database of more than 340 billion clinically validated data points to distinguish between healthy and damaged tissue. The DeepViewTM System can be used immediately upon a child's arrival to the emergency department or burn center, providing immediate and accurate wound assessments in support of timely clinical decision-making for burn injuries. The procedure is non-invasive and because it is cart-based, the DeepViewTM System can be brought to the patient, thus alleviating any potential trauma associated with moving an injured child.

About Spectral Al

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. The DeepView System is a predictive 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 to change the current standard of care, the DeepView System 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 the DeepView System, 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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