Spectral AI Surpasses 90% of Pediatric Enrollment Target in Burn Centers for Pivotal U.S. Burn Study

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DALLAS, June 27, 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 surpassed 90% of the enrollment target for pediatric patients at burn centers for its 2024 pivotal study designed to validate the AI-driven algorithm used by its DeepView™ System for its burn indication.

"We are excited with the progress on enrollment of pediatric subjects, which has exceeded our expectations given the difficulties normally experienced in trials for this age group," said Peter M. Carlson, CEO of Spectral AI. "We continue to enroll adult and pediatric subjects at both burn centers and emergency departments for our 2024 pivotal study."

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

For both adults and children, an accurate wound assessment is critical in determining the appropriate treatment protocol. However, the assessment of pediatric patients in comparison to adults poses distinct challenges. Pediatric skin is thinner and contains less subcutaneous fat than that of an adult, making it more challenging to assess the depth of the burn injury, and systemic responses to a burn injury differ from those of an adult patient. The age of the patient, their communication skills, and stage of development also serve as differentiating factors when treating a child.

"More than 100,000 children are admitted to a hospital or treated in an emergency department for burn injuries each year," Mr. Carlson noted. "The type, scope, and manner of care that must be delivered to children underscores our belief that empowering clinicians to deliver an immediate, accurate assessment of pediatric burn wounds is of critical importance."

Spectral AI'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 DeepView™ 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 DeepView™ System can be brought to the patient, thus alleviating any potential trauma associated with moving an injured child.

"The time surrounding a burn injury is often stressful for children and their families. It is a time of great uncertainty," said Dr. Kathleen Romanowski, Principal Investigator at one of the clinical trial sites, Shriners Children's Northern California Neil Reitman Pediatric Burn Institute. "We anticipate Spectral AI's DeepView™ System will allow practitioners to eliminate some of that uncertainty through early identification of burn depth and the potential need for surgical treatment."

The pivotal clinical study is designed to: validate the standalone performance of the DeepView™ System's AI-driven algorithm on an independent dataset, further solidifying its objective utility in clinical practice and compare the efficacy of the DeepView™ System's finalized image processing algorithm against existing clinician assessment, as quantified by clinician judgment annotations.

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. 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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