



Spectral AI Achieves 25% Patient Enrollment at Emergency Departments for U.S. Burn Pivotal Study and Adds Two New Clinical Trial Sites

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DALLAS, Sept. 24, 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 25% patient enrollment at Emergency Departments ("ED") for its U.S. Burn Pivotal Study and added two new ED Clinical Trial Sites for this study: MedStar Washington Hospital Center in Washington, DC led by Principal Investigator Shawn Tejiram, MD and the University of Utah led by Principal Investigator Giavonni Lewis, MD, FACS. The addition of these two clinical research sites expands participating EDs to 11 facilities.

One of the largest domestic burn studies ever conducted, the U.S. Burn Pivotal Study is designed to validate the AI-driven algorithm used by the Company's DeepView[®] System for burn indication ("DeepView AI[®]-Burn").

"We are continuing to build momentum and advance towards achieving our ED enrollment goals," said Peter M. Carlson, Chief Executive Officer of Spectral AI. "Access to specialized burn treatment in the United States has declined significantly, resulting in an increasing number of front-line ED clinicians assuming the initial responsibility of assessing the severity and healing trajectory of a burn wound. We believe that the use of DeepView AI[®]-Burn can deliver burn expert-level clinical support to a busy, oftentimes chaotic, ED setting."

As previously announced, the Company has completed both adult and pediatric patient enrollment at U.S. burn centers for the U.S. Burn Pivotal Study. Using data from these burn center patients, the Company will pursue a De Novo submission to the U.S. Food and Drug Administration ("FDA") requesting classification of DeepView AI[®]-Burn as a Class II medical device. The Company expects to submit this request to the FDA in the second quarter of 2025.

Spectral AI's DeepView[®] System for burn indication is designed to distinguish between healing and non-healing tissue by providing an immediate and binary prediction of wound healing on Day One that can support clinical decision-making regarding next step treatment plans.

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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