Spectral AI Completes Burn Center Enrollment for U.S. Burn Pivotal Study

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Milestone Achievement Advances Commercialization Timeline for DeepView™ System for Burn Indication

DALLAS, Aug. 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 the completion of adult and pediatric patient enrollment at U.S. burn centers for its U.S. Burn Pivotal Study. 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.

Using data from these burn center patients, the Company will pursue a De Novo classification from the U.S. Food and Drug Administration ("FDA") for use of the DeepView™ System in burn centers and expects to submit the request in the second quarter of 2025.

"We met our burn center enrollment goal much sooner than anticipated due to the dedication of our team and the support of study participants," said Peter M. Carlson, Chief Executive Officer of Spectral AI. "This milestone achievement will allow us to begin data analysis and advances our product commercialization timeline," Carlson added.

Spectral AI's DeepView™ System for burn indication is a predictive medical device that assesses the healing potential of burns by combining multi-spectral imaging with an AI-driven algorithm trained and tested against a proprietary database of more than 340 billion clinically validated data points. By distinguishing between healing and non-healing tissue, the DeepView™ System provides an immediate and binary prediction of wound healing on Day One that can support clinical decision-making regarding next step treatment plans. The DeepView™ System has demonstrated superior accuracy in assessing burn wounds compared to the current standard of care.

"I am proud of the incredible work by our investigators, their dedicated staff and most critically study enrolees," stated Dr. Jeffrey Carter, MD, Principal Investigator of the Pivotal Study. "We enrolled 160 patients in less than eight months, in what we believe to be one of the fastest enrolling burn studies ever completed in the U.S. The results will be used by our data science team and our panel of burn experts to complete years of work and bring this crucial advancement in burn wound assessment to patients and providers in the U.S."

The Company is continuing to enroll patients at Emergency Departments (ED) as part of the U.S. Burn Pivotal Study, with such enrollments expected to continue into 2025. A subsequent 510(k) application will be submitted for the use of the DeepView™ System in EDs following the completion of the ED enrollment, associated data analysis, and the receipt of FDA approval for the use of the DeepView™ System in burn centers.

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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