Spectral AI Announces Last Patient Out in U.S. Burn Pivotal Study at Burn Centers

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Milestone Achievement Supports Planned FDA Submission of DeepView AI®-Burn in 2025

DALLAS, Oct. 30, 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 the final group of burn center patients in the Company's U.S. Burn Pivotal Study have successfully completed their clinical visits.

One of the largest domestic burn center studies ever conducted, the U.S. Burn Pivotal Study is expected to be the final clinical trial before the Company seeks U.S. Food and Drug Administration ("FDA") approval of its DeepView ® System for burn indication ("DeepView AI ®-Burn") in the first half of 2025. DeepView AI®-Burn is a non-invasive, predictive medical device designed to distinguish between healing and non-healing tissue in order to provide clinicians with an immediate and binary assessment of a burn wound's healing potential.

The Company expects to report topline results from this study in December 2024.

"The completion of this aspect of the U.S. Burn Pivotal Study marks a critical milestone on our path towards commercialization," said Dr. J. Michael DiMaio, Chairman of the Board. "These results will form the foundation of our forthcoming U.S. regulatory submission and brings us one step closer to delivering a potentially groundbreaking advancement in burn wound assessment that can support clinical decision-making regarding next step treatment plans, broaden equity in access to burn care treatment, and improve clinical outcomes. I want to thank our investigators, their dedicated staff, and study enrollees for their support in this endeavor."

About the U.S. Burn Pivotal Study

The U.S. Burn Pivotal Study was initiated in January 2024 and involves 160 adult and pediatric patients at 14 burn centers across the country. It is designed to validate the AI-driven closed loop algorithm used by DeepView AI®-Burn. Each patient underwent non-invasive imaging of their wound using DeepView AI®-Burn beginning at the initial clinical assessment and until the treatment plan was defined. An end image was required at 21 days following initial assessment.

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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