



Spectral AI Announces Successful Results from its Burn Validation Study of the DeepView System

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- ***DeepView[®] System outperforms burn physicians in identifying non-healing tissue***
 - ***Landmark Burn Validation Study, one of the largest in U.S. history, confirms DeepView's performance***
- ***Spectral AI plans FDA submission by mid-2025, targeting De Novo Clearance and rapid commercialization to transform burn care***

DALLAS, March 17, 2025 (GLOBE NEWSWIRE) -- **Spectral AI (NASDAQ: MDAI)** ("**Spectral AI**" or the "**Company**"), developer of the AI-driven DeepView[®] System, that uses multi-spectral imaging and AI algorithms to predict burn healing potential, announced the successful results of the performance of its DeepView System in connection with the completion of its Burn Validation Study. Spectral AI's DeepView System is being developed as a predictive device to offer clinicians an immediate and objective assessment of a burn wound's healing potential prior to treatment or other medical intervention. The image processing algorithm employed by the DeepView System utilizes multispectral imaging that is trained and tested against a proprietary database of more than 340 billion clinically validated data points. The DeepView System is non-invasive and cart-based, allowing for exceptional mobility within the healthcare setting.

The Burn Validation Study, which began in January 2024 and concluded in March 2025, represented one of the largest burn trials ever conducted in the United States. The Company enrolled and analyzed data obtained from 164 total patients comprised of 115 adult and 49 pediatric patients in burn centers and emergency departments across the U. S. in its Burn Validation Study. The goal of the Burn Validation Study was to further demonstrate the innovative and versatile nature of Spectral AI's DeepView technology, as well as its ability to predict burn wound healing potential on the first day of injury with greater performance and speed than the methods currently used today. The Burn Validation Study results, together with rigorous statistical analysis, illustrate that the DeepView System continues to outperform the clinical judgment of burn physicians by a large margin.

The Burn Validation Study results assessed the sensitivity, specificity and Dice score of the DeepView System at both a pixel-level and image-wise level against the clinical judgment of burn physicians. Key findings included the following:

- **Sensitivity:** The DeepView System demonstrated a statistically significant improvement in identifying non-healing tissue compared to burn physicians, as judged on sensitivity. At the image-wise level, the DeepView System scored 86.6% while clinical judgment annotation (CJA) of burn physicians scored 40.8%. At the pixel-wise level, the DeepView System scored 81.9% and CJA of burn physicians scored 38.8%.
- **Dice Score:** The DeepView System achieved statistically significant higher Dice Scores when compared to those derived from burn physicians' CJA, representing the improved pixel-wise evaluation between predicated and true segmented wound areas with the DeepView System performing at 68.5% and burn physician's CJA at 39.2%.
- **Specificity:** The Deepview System significantly outperformed the anticipated results for image-wise specificity in segmenting non-healing wound areas with a result of 61.2% (versus an anticipated result of 36.0%) and CJA of 79.1% reflecting burn physician's conservative assessment of burn areas.

"We believe these are excellent results and we are thrilled with the analysis of our DeepView System in our Burn Validation Study," said Dr J. Michael DiMaio, M.D. "The DeepView System exceeded our expectations in terms of predictive performance. Following the FDA's review, if authorized by the agency, our hope is that this tool will provide an objective and immediate prediction of non-healing burn tissue to expedite patient care and reduce system costs across the board. I would like to thank Jeffrey C. Carter, MD, FACS, the principal investigator for the Burn Validation Study, our entire team at Spectral AI, and especially the patients and esteemed clinicians who participated in this Study. We look forward to bringing this predictive diagnostic tool to the United States marketplace as soon as possible."

Spectral AI plans to submit these results to the FDA as part of its regulatory submission by the end of the second quarter of 2025 and hopes to have the FDA grant the De Novo Classification Request of the DeepView System in early 2026. Based on its current manufacturing arrangements, Spectral AI will be prepared to commercialize the DeepView System in the United States, if ultimately approved, as soon as approval is obtained.

This project is being supported in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; BARDA, under contract number 75A50123C00049.

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. The Company is working to revolutionize the management of wound care by "Seeing the Unknown[®]" with its DeepView[®] System. The DeepView[®] System is being developed as a predictive device to offer clinicians an objective and immediate assessment of a burn wound's healing potential prior to treatment or other medical intervention. With algorithm-driven results and a goal of exceeding the current standard of care in the future, the DeepView[®] System is expected to provide fast and 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.

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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.

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