Spectral AI Completes Truthing of Burn Center Images, Initiates Emergency Department Image Review

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DALLAS, Dec. 02, 2024 (GLOBE NEWSWIRE) -- Spectral AI (NASDAQ: MDAI) (“Spectral AI” or the “Company”), an artificial intelligence (AI) company focused on revolutionizing medical diagnostics to enable faster, more accurate treatment decisions in wound care, today announced the successful completion of truthing for all images gathered from burn centers across the United States. This milestone represents a pivotal step in training the Company's proprietary DeepView® System to predict wound healing outcomes accurately. Having completed the process for burn centers, Spectral AI is now initiating truthing for images collected from emergency departments and emergency rooms nationwide, expanding the scope of the DeepView® System's capabilities.

Truthing is the rigorous process of gathering ‘ground truth’ data that verifies whether portions of a wound did or did not heal and then using this data for training of its AI-powered algorithm. For each patient, images are collected during the early stages of treatment and correlated with biopsies, 21-day wound assessments, and expert evaluations. This combination of data creates a "ground truth" dataset, enabling the DeepView® System to distinguish between wounds likely to heal and those requiring intervention.

"By completing the truthing process for burn centers, this adds to Spectral AI's largest comprehensive tissue dataset, encompassing over 3,000 biopsied images," said Dr. J. Michael DiMaio, Chairman of Spectral AI's Board of Directors. "This achievement reflects collaboration between internationally recognized burn experts, skilled dermatopathologists, and our dedicated engineers and data scientists. This multidisciplinary effort ensures that our technology evolves with precision and reliability, surpassing the limitations of traditional diagnostic methods."

The Company's Burn Biopsy Algorithm (BBA), developed alongside leading experts, integrates advanced machine learning with clinical insights, allowing the DeepView® System to identify healing trajectories with unprecedented effectiveness. By leveraging data from the largest burn tissue bank ever assembled, the DeepView® System is designed to provide clinicians with actionable information and reducing guesswork.

Now, Spectral AI is expanding its focus to emergency departments, where the stakes are equally high. The truthing process will include data collected during the critical early stages of care, enabling the DeepView® System to adapt to a broader range of clinical scenarios.

“Our team is committed to ensuring the DeepView® System delivers unparalleled diagnostic accuracy,” said Dr. DiMaio. “By incorporating data from diverse care settings, we aim to create a solution that seamlessly integrates into workflows across the spectrum of acute care."

Spectral AI has successfully enrolled and completed image collection for the BARDA burn study, a critical step in training the AI algorithm for the DeepView AI®-Burn device. The Company anticipates data results in late December to support an FDA De Novo submission in the first half of 2025, which seeks to classify the DeepView AI®-Burn system as a Class II medical device. Designed for use in multiple medical settings, the DeepView AI®-Burn system provides fast and accurate burn-depth assessments, empowering clinicians to make informed, early treatment decisions and improving care for both adult and pediatric burn victims.

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 wound care management by "Seeing the Unknown®" with its DeepView® System. DeepView 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 of exceeding the current standard of care in the future, DeepView is expected to provide faster and more accurate treatment insight toward value care by improving patient outcomes and reducing healthcare costs. For more information about DeepView, 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 intention to separate its Spectral IP subsidiary from the Company, and each Company’s strategy, plans, objectives, initiatives, strategic goals, financial outlook or other non-historical matters. 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. Spectral AI undertakes no obligation to update any forward-looking statements except as otherwise required by law.

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