Spectral AI Announces Submission to FDA of its DeepView® System

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DALLAS, June 30, 2025 (GLOBE NEWSWIRE) -- **Spectral AI (NASDAQ: MDAI) ("Spectral AI" or the "Company")**, developer of the AI-driven DeepView® System, which received Breakthrough Device Designation from the U.S. Food and Drug Administration ("FDA") in 2018 and uses multi-spectral imaging and artificial intelligence ("AI") algorithms to predict burn healing potential, today announced the submission of its De Novo 510k marketing clearance application to the FDA for the DeepView System, intended for use in burn care settings, including both burn centers and emergency departments. The De Novo regulatory pathway is being pursued due to the novel nature of this technology, which does not have a predicate device currently available in the U.S. market.

Spectral AI's DeepView System is a non-invasive, predictive medical device and associated software platform that combines multispectral imaging with a proprietary AI algorithm to assess the healing potential of burn wounds. The DeepView System provides clinicians with a non-healing prediction—on the same day of injury and up to a week (7 days) post injury, enabling earlier and more informed treatment decisions.

"This FDA submission is a major milestone for Spectral AI and the DeepView System, representing a crucial step toward bringing this innovative diagnostic device to market in the United States. It provides clinicians with an immediate, data-driven assessment tool designed to assist clinical decision-making and may significantly improve patient outcomes," stated Dr. J. Michael DiMaio, MD, Chairman of the Board at Spectral AI. "I am grateful to our shareholders for their continued support as we reach this important milestone in submitting the De Novo request to the FDA for the DeepView System," DiMaio said. "I am also incredibly proud of our team's dedication and remain confident in our mission to bring this technology to the broader healthcare market worldwide."

This project is being supported in whole or in part with federal funds from the U.S. Department of Health and Human Services; Administration for Strategic Preparedness and Response; BARDA, under contract number 75A50123C00049 with its wholly-owned subsidiary Spectral MD, Inc. Since 2013 and prior to this contract, the advance development of this technology has been supported in two previous contract awards under contract numbers 75A50119C00033 and HHSO100201300022C.

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.

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.

For Media and Investor Relations, please contact:

David Kugelman
Atlanta Capital Partners LLC
(866) 692-6847 Toll Free - U.S. & Canada
(404) 281-8556 Mobile and WhatsApp
Email: dk@atlcp.com