Spectral AI Reaches 50% Enrollment at Burn Centers for U.S. Pivotal Burn Study

Jun 06, 2024

Total Patient Enrollment of 90 Towards Overall Target of 240

DALLAS, June 06, 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 it has achieved 50% clinical trial site enrollment at burn centers for its 2024 pivotal study designed to validate the algorithm used by its DeepView™ System for burn indication. This pivotal study, which is targeting enrollment of 240 patients, including both adult and pediatric subjects at multiple burn centers and emergency departments across the U.S., is expected to be the final clinical trial before seeking FDA approval in 2025.

The completion of the pivotal study will address two primary objectives. First, the study will validate the standalone performance of the DeepView™ System's algorithm on an independent dataset, further solidifying its objective utility in clinical practice. Second, the study will compare the efficacy of the DeepView™ System's finalized image processing algorithm against existing clinician assessment, as quantified by clinician judgment annotations.

"We are committed to advancing burn care through the implementation of innovative technologies and rigorous clinical research. Our objective is to deliver to healthcare providers the cutting-edge tools they need to enhance their ability to immediately and accurately assess a burn wound's healing potential," stated Mary Regan, VP of Medical Affairs at Spectral AI. "We are enthusiastic about the achievement of this enrollment milestone as we aim to demonstrate DeepView's AI effectiveness in providing accurate wound assessments and timely clinical decision-making for burn injuries."

"As clinicians, our goal is to provide the best possible care for burn patients, utilizing the latest medical advancements and techniques," said Dr. Kathleen Romanowski, Principal Investigator at one of the clinical trial sites, the UC Davis Firefighters Burn Institute Regional Burn Center. "DeepView's technology has the potential to significantly enhance our ability to assess burn wounds accurately, leading to improved patient outcomes and quality of life."

The Company's DeepView™ System image processing algorithm utilizes multispectral imaging, trained and tested against a proprietary database of more than 340 billion clinically validated data points, to deliver a rapid and objective assessment that aids healthcare providers in assessing the healing potential of a burn wound. The U.S. pivotal study is currently enrolling patients at several leading burn centers in the U.S., with esteemed Principal Investigators overseeing the research.

A list of the burn centers currently enrolled in the Company's U.S. pivotal study is below.

U.S. Clinical Trial Sites	**Principal Investigator**
Arizona Burn Center Valleywise Health	Dr. Kevin Foster
VCU Health Evans-Haynes Burn Center	Dr. Michael Feldman
St Christopher's Stuart J. Hulnick Burn Center	Dr. Paul Glat
UC Davis Firefighters Burn Institute Regional Burn Center	Dr. Kathleen Romanowski
Shriners Children's Northern California Neil Reitman Pediatric Burn Institute	Dr. Kathleen Romanowski
UW Harborview Regional Burn Center	Dr. Tam Pham
University of Kansas Burnett Burn Center	Dr. Dhaval Bhavsar
North Carolina Jaycee Burn Center	Dr. Booker King
SUNY Stony Brook Burn Center	Dr. Adam Singer
Akron Children's Hospital Burn Institute	Dr. Anjay Khandelwal
University of Iowa Burn Treatment Center	Dr. Lucy Wibbemeyer
The Ohio State Comprehensive Burn Center	Dr. Nicole Bernal

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. 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 to change the current standard of care, DeepView 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 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 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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