



U.S. Burn AI Clinical Training Study Enrollment Completed

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Successful completion of clinical study enrollment paves way for next phase of BARDA funding

Data used to finalize DeepView AI®-Burn algorithm

LONDON, U.K. AND DALLAS, TX, U.S. -Spectral MD Holdings, Ltd. (AIM: SMD), a predictive analytics company with proprietary artificial intelligence (AI) algorithms and optical technology for faster and more accurate treatment decisions in wound care, announces the completion of enrollment for its U.S. Burn AI Training Study ("Training Study") supported by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services.

The Company is using the data collected from adult and pediatric subjects enrolled in the study to finalize the DeepView AI®-Burn algorithm and make sample size determinations for its U.S. Burn AI Validation Study ("Validation Study"), which is expected to start in H2 2023.

The Training Study was performed across 11 leading burn centers in the U.S., and was expanded in [August 2022](#) with BARDA's support, to include additional pediatric sites and U.S. Emergency Departments ("EDs"). Enrollment completion fulfills this phase of the Company's contractual requirements with BARDA. The Company is aligning its efforts to complete the necessary requirements for the upcoming Validation Study.

The Validation Study will generate an independent dataset with subjects enrolled across different U.S. study sites from the Training Study. This is a requirement for the U.S. Food and Drug Administration (FDA) to remove bias from the results ahead of the Company's DeepView AI®-Burn FDA regulatory submission, planned in 2024.

Wensheng Fan, Chief Executive Officer of Spectral MD, stated: "The completion of enrollment in our Burn AI Training Study represents a significant milestone for Spectral MD, as it meets our contractual obligations with BARDA, paving the way for the final stage of clinical development for DeepView AI®-Burn. With BARDA's invaluable support, we anticipate initiating our Burn AI Validation Study in the second half of 2023, and we remain committed to our partnership to deliver a non-invasive imaging platform for the U.S. government that enables physicians to accurately and instantaneously assess the severity of burns in mass-casualty events."

Dr. Jeffrey Carter, Chief Medical Consultant, and National Principal Investigator for the Training Study, said: "Today's milestone represents another exciting step forward as we advance the development of the DeepView™ technology for burn wound healing assessment. We successfully reached study enrollment completion on schedule, in our largest clinical trial to date, reflecting the high interest from patients and physicians in a 'Day One' burn wound healing assessment."

Currently, there are only 250 burn surgeons in the U.S., or 0.3% of the 84,000 members of the American College of Surgeons. The decline in burn experts, education, and experience has left large regions of the U.S. without the ability to accurately assess burn wound healing or burn wound size, resulting in unnecessary transfers from EDs to burn centers, and unnecessary days in the hospital while surgeons reassess burn wounds for surgery. DeepView™ uniquely addresses these challenges by aiding clinicians in accurately assessing burn wound healing potential on 'Day One'. DeepView AI®-Burn currently has a wound healing diagnostic accuracy of 92%, significantly above physician clinical judgement accuracy of between 50-75%.

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About Spectral MD:

We are a dedicated team of forward-thinkers striving to revolutionize the management of wound care by "Seeing the Unknown" © with our DeepView® Wound Imaging System.

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