Spectral MD Completes Expanded Proof-of-Concept (ePOC) Multi-Center Clinical Study for Burn Wounds

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Spectral MD's DeepView imaging device collected data from 124 Adult and Pediatric Subjects to further develop its burn wound-healing prediction AI Algorithm

Spectral MD announced today the completion of an IRB-approved multi-center study to support the development of its DeepView Wound Imaging System. Building upon promising results from a 2019 Proof-Of-Concept study, Spectral MD continues to bolster its existing clinical database of burn wound images and physiological information to train and improve the diagnostic accuracy of the AI algorithm.

The ePOC study enrolled a total of 124 patients and is an important milestone for the company in fulfilling its contractual requirements under the company's existing contract with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services. The company is working to provide BARDA and the United States government with a non-invasive imaging platform that can accurately assist physicians with instantaneous surgical triage of burn patients in a mass-casualty event. Despite COVID-19, this complex study was executed successfully and on schedule across three clinical sites: Wake Forest Baptist Medical Center Winston-Salem, University Medical Center New Orleans, and Medstar Washington Hospital Center D.C.

Led by James H. Holmes IV, MD and Jeffrey E. Carter, MD, the clinical teams at Wake Forest Baptist Medical Center Winston-Salem and University Medical Center New Orleans respectively have been instrumental in guiding this complex study across multiple sites. As their experienced clinical staff also participated in previous clinical studies with Spectral MD, they facilitated knowledge transfer across the multiple clinical sites for all critical protocol, which include DeepView imaging and ground truthing methodology.

Dr. Holmes, Professor and Medical Director at Wake Forest Baptist Medical Center Winston-Salem Burn Center and National Principal Investigator for the ePOC Study, stated, "Completion of this study is a significant step towards making this revolutionary technology available to patients. Once approved by the FDA, we anticipate that DeepView will produce material changes in how we manage burn patients day-to-day and provide a significant triage tool for use in burn mass-casualty incidents. Ultimately, this all translates into improved outcomes for burn patients."

Dr. Phelan, burn surgeon and Principal Investigator for the ePOC Study at University Medical Center New Orleans, affirmed, "It's testimony to the dedication and experience of our teams that not only did we complete this study in a timely and rigorous manner, but we did so against the headwinds of the COVID-19 pandemic as well. To a person, our research partners' drive is fueled by our belief in this technology and the benefits it holds for future burn patients."

Dr. Carter, Medical Director at University Medical Center New Orleans Burn Center and Chief Medical Consultant for Spectral MD, explained, "The burden of a global pandemic can inhibit scientific advancement as healthcare teams respond to the emergent needs of their communities. Fortunately, our team of investigators responded to the crisis while continuing to care for those suffering severe burn injuries. Their work with the creative and committed staff at Spectral MD helped overcome numerous obstacles leading to substantial improvements in the burn diagnostic algorithm and the establishment of the largest reported burn biopsy database. These achievements are monumental and demonstrate the promise and potential of the team and the technology."

"Completing enrollment for this study is a major milestone toward advancing our device's performance, and in our ability to characterize its performance across a wide range of burn injuries including pediatric burns," said Dr. Jeffrey Thatcher, Chief Scientist for Spectral MD. "We are excited to work toward completion of the analysis phase of the study, the results of which are key indicators for planning the critical final stages of device development and validation."

Funding and technical support for development of DeepView® Wound Imaging System are provided by the Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG Contract No. 75A50119C00033. For more information about BARDA, refer to https://www.medicalcountermeasures.gov.

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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