



Diabetic Foot Ulcer Clinical Validation Study Initiated

Jun 13, 2022

Validation study to assess up to 200 adult subjects with participation from leading U.S. principal investigators

LONDON, U.K AND DALLAS, TX, U.S. Spectral MD Holdings, Ltd. (AIM: SMD), a predictive analytics company that develops proprietary AI algorithms and optical technology for faster and more accurate treatment decisions in wound care, announces the start of its clinical validation study to support the development of its Diabetic Foot Ulcer (“DFU”) application for the DeepView® Wound Imaging System. The proprietary technology combines multi-spectral imaging and Artificial Intelligence (AI) to provide clinicians with an immediate healing assessment for DFU, which enables clinicians to provide a more accurate and timely diagnosis for therapeutic intervention.

The study will collect data from up to 200 adult subjects across seven potential clinical sites to further develop DeepView®’s AI algorithm. Patient enrollment for the validation study began this month and is expected to complete in November 2022.

Building upon promising results from the clinical training study, where the current diagnostic accuracy is 81%, the data collected from the validation study will be used to bolster the Company’s existing clinical database of DFU images and physiologic information to train and improve the DeepView® AI algorithm. Additionally, the validation study will collect data from a broader population set of up to 200 subjects to increase geographic and ethnic variability. Importantly, data collected will support the Company as it prepares FDA and CE mark submissions for DeepView®’s DFU indication, planned in 2023.

Participating investigators include: Dr. Alisha Oropallo, MD, Director of Comprehensive Wound Healing Center at Northwell Health; Dr. Brock Liden, DPM, Podiatry Specialist at Circleville Foot & Ankle Center, LLC; and Dr. Babajide Ogunlana, DPM, West Houston Foot and Ankle Center. Additional clinical sites are being evaluated and will be incorporated into the validation study in the near future.

Dr. Alisha Oropallo, M.D., FACS, FSVS, Director of Comprehensive Wound Healing Center at Northwell Health and National Principal Investigator for the study, commented: *“For patients with diabetes, foot ulcers can impact their quality of life and lead to complicated infections and potential amputation. I look forward to participating in this study as DeepView® has significant potential to improve the current standard of care, resulting in faster application of advanced therapy, better wound healing and reduced overall hospital visits and utilization.”*

Mary Regan, PhD, VP of Clinical Affairs at Spectral MD, said: *“We are very pleased to have initiated the Clinical Validation Study, the next critical step towards the completion of development for the DFU application for DeepView® Wound Imaging System. To obtain robust clinical data, the Spectral MD team has selected leading wound care providers to advance and develop our DeepView® Wound Imaging technology. I look forward to working with all participating clinical sites to ensure high quality data and clinical engagement.”*

Market Abuse Regulation (MAR) Disclosure

The information contained within this announcement is deemed by the Company to constitute inside information as stipulated under the Market Abuse Regulations (EU) No. 596/2014 as it forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018 (‘MAR’). Upon the publication of this announcement via Regulatory Information Service (‘RIS’), this inside information is now considered to be in the public domain.

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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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About Diabetic Foot Ulcer

DFU is a severe chronic diabetic complication that consists of lesions in the deep tissues associated with neurological disorders and peripheral vascular disease in the lower limbs. It is the most frequently recognized, complex and costly symptom of diabetes and can lead to limb amputation if left undiagnosed, misdiagnosed or untreated. Due to U.S. reimbursement rules, physicians are currently required to wait 30 days to designate a DFU as non-healing before using advanced wound care therapies, resulting in higher probability of infections, longer healing times and significant lifetime

medical costs for the patient. DeepView®'s early healing assessment for DFU would provide a significant improvement to the current standard of care, resulting in faster application of advanced therapy, better wound healing and reduced overall hospital visits and utilization.