



EU Diabetic Foot Ulcer Clinical Study Initiated in Ireland

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Data from the study to support regulatory submissions on track for 2023

Participation from distinguished EU principal investigators provides significant endorsement for DeepView™

LONDON, U.K. AND DALLAS, TX, U.S. -Spectral MD Holdings, Ltd. (AIM: SMD), a predictive analytics company with proprietary AI algorithms and optical technology for faster and more accurate treatment decisions in wound care, announces the initiation of its EU clinical study to support the development and regulatory submission of its Diabetic Foot Ulcer (DFU) application for the Company's DeepView™ technology.

The Company has partnered with the Royal College of Surgeons in Ireland's (RCSI) Skin Wounds and Trauma (SWaT) Research Centre, Prof. Zena Moore, Director; and Prof. Declan Patton, Deputy Director, at RCSI University of Medicine and Health Sciences, to execute the clinical study with Prof. John McDermott (Chief Clinical Investigator) and Prof. Seamus Sreenan (Sub Investigator), both of Connolly Hospital, and RCSI in Dublin, Ireland.

The EU Wound Assessment Using Spectral Imaging clinical study will collect data from DFU patients monitored up to 12 weeks. The intention of the clinical study is to further develop the DeepView AI@-DFU algorithm and support the Company's 2023 regulatory submissions for UK CA, US FDA, and EU CE Mark.

Chronic wounds, such as DFU, affect 9.1 to 26.1 million patients globally each year, and are the most frequently recognized, complex and costly symptom of diabetes. Globally, 70% of DFUs recur within three years, representing a significant health and economic burden to both patients and hospital systems. Additionally, undiagnosed, misdiagnosed, or untreated DFUs commonly lead to limb amputation and poor patient outcomes.

There is currently no diagnostic tool available for early wound healing diagnosis, with physicians required to wait 30 days to designate a DFU as non-healing before using advanced wound care therapies. Early and accurate diagnosis of non-healing DFUs would considerably improve patient quality of life and DFU healing rates. The Company announced in [January 2023](#) interim results for DeepView AI@-DFU's day-one prediction of 86% diagnostic accuracy of a 50% DFU size reduction by week four from five clinical study sites in the US, and this EU clinical study data will enhance its clinical database and strengthen the regulatory and clinical pathways.

Prof. Zena Moore and Prof. Declan Patton of the RCSI SWaT Research Centre jointly commented: *"With our clinical partners we are committed to better wound care diagnostics and treatment for patients. This study will ensure we continue to be at the cutting edge of clinical wound care research that makes a difference to people with non-healing ulcers. Working with Spectral MD also enhances our place at the forefront of medical device research and translation for everyday wound care practice."*

Wensheng Fan, Chief Executive Officer of Spectral MD, stated: *"The initiation of the EU study is an important milestone for the Company. We are delighted by this industry-academic partnership led by a group of eminent clinicians and clinical researchers, which we see as a significant industry-wide endorsement for DeepView™. Data collected from this collaboration will strengthen the predictive capability of the DeepView™ technology for early stage wound assessment."*

Prof. Fergal O'Brien, Deputy Vice-Chancellor for Research and Innovation at RCSI, commented: *"By bringing together the research expertise of the SWaT Research Centre at RCSI with the advanced technological capabilities of Spectral MD, this study is driving forward wound care technology development to address a significant unmet need by improving diagnostic imaging and quantitative diagnosis and ultimately patient outcomes."*

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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 RCSI University of Medicine and Health Sciences

RCSI University of Medicine and Health Sciences is a world-leading university for Good Health and Well-being. Ranked in the world top 50 for its contribution to UN Sustainable Development Goal 3 in the Times Higher Education Impact Rankings 2022, it is exclusively focused on education and

research to drive improvements in human health worldwide.

RCSI is an international not-for-profit university, headquartered in Dublin. It is among the top 250 universities worldwide in the World University Rankings (2023). RCSI has been awarded Athena Swan Bronze accreditation for positive gender practice in higher education.

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