Positive Interim Results from DFU Clinical Study & Burn Clinical Study Update

Jan 18, 2023

DeepView® accuracy increases to 86% in diagnosis of DFU healing potential on day one

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 interim results for its Diabetic Foot Ulcer ("DFU") Clinical Study, initiated in June 2022. The DeepView® Wound Imaging System diagnostic accuracy calculated in the interim analysis, being the prediction of a 50% DFU size reduction by week four, has improved five-percentage points to 86% on day one. This increase in diagnostic accuracy will strengthen the Company's planned 2023 FDA submission for its DeepView® DFU indication.

The four-week milestone in DFU reduction in the clinical treatment pathway for a DFU patient is meaningful to determine if alternative treatment is needed. The interim analysis was performed with an initial 100 U.S. adult subjects out of the targeted 200 subjects enrolled, and showed:

- 86% diagnostic accuracy, from the previously reported 81%
- 89% sensitivity
- 83% specificity

Currently, there are no diagnostic tools available in DFU healing prediction. The standard of care for DFU relies on physicians using a wait-and-see approach of up to 30 days to determine if there is a need for advanced intervention.

The DFU study is currently running at five clinical sites in the U.S. As the Company's regulatory strategy evolves, it is adding additional clinical sites, three contracted, to ensure study completion in 1H 2023. The Company plans to announce additional EU/UK DFU clinical studies in the near future and will provide updates accordingly. The Company remains on track to complete its FDA 2023 regulatory submission.

Niko Pagoulatos, Chief Operating Officer of Spectral MD, said: *"We are encouraged by the interim observations from the DFU Clinical Study, and we look forward to completing enrollment to finalize DeepView® DFU indication performance analysis and to submit for regulatory approvals. The results from the interim analysis further validate how the DeepView® technology could significantly help transform the lives of people suffering from Diabetic Foot Ulcers."*

Dr. Brock Liden, Podiatry Wound Specialist at Wound and Feet Liden and Principal Investigator in the DFU Clinical Study, commented: *"These are extremely encouraging results that show the incredible potential of DeepView® to significantly transform how we treat, manage, and assess Diabetic Foot Ulcers. Diabetic Foot Ulcers are unusually challenging due to the many comorbidities associated with diabetes, which may interrupt the healing process. I look forward to the continued collaboration with Spectral MD as we work to collect meaningful data to further validate this transformative technology."*

Burn Indication Update:

The Company has been working on the BARDA funding contract for the Burn indication, and the recent US$ 8.2 million contract expansion with BARDA continues to support interoperability features and commercial readiness for the DeepView® Wound Imaging System. The updates for the current DeepView® Burn AI Training Study are:

- Since year end 31 December 2022, adult enrollment is complete.
- The study population covers demographic and geographic variability.
- The study is currently performed at 11 world-renowned research hospitals, with additional pediatric research sites established.
- Study is expected to be completed 1H 2023.

Spectral MD is in constant communication with BARDA to further develop its infrastructure readiness for a federal level commercial contract.

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.

For further information please contact:

Spectral MD Holdings, Ltd.	investors.spectralmd.com
Wensheng Fan, Chief Executive Officer	via Walbrook PR
Nils Windler, Chief Financial Officer	
SP Angel Corporate Finance LLP (NOMAD and Joint Broker)	Tel: +44 (0)20 3470 0470
Stuart Gledhill/Caroline Rowe (Corporate Finance)Vadim Alexandre/Rob Rees (Sales & Broking)	

Stifel Nicolaus Europe Limited (Joint Broker) Charles Hoare / Ben Maddison / Nick HarlandWill Palmer-Brown

Tel: [+44 (0)20 7710 7600](#)

Walbrook PR Ltd (Media & Investor Relations)

Paul McManus / Louis Ashe-Jepson /Sam Allen

Tel: [+44 (0)20 7933 8780](#) or [spectralMD@walbrookpr.com](#)

Mob: [+44 (0)7980 541 893](#) / [+44 (0)7747 515 393](#) [+44 (0)7502 558 258](#)

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.

[www.spectralmd.com](#)

[info@spectralmd.com](#)