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FDA expert panel in line with SciBase position to keep stringent approval level for all new skin lesion analyzers

STOCKHOLM, SWEDEN, — August 9, 2022 – SciBase Holding AB ("SciBase") [STO:SCIB], a leading developer of augmented intelligence-based solutions for skin disorders, announced today that the FDA (US Food and Drug Administration) held a meeting with the Medical Devices Advisory Committee on July 28th and 29th to gather expert advice on the regulation of AI driven, skin lesion analyzers (SLAs) and Apps for skin cancer detection.

Panel members urged caution for skin cancer detection SLAs and Apps and stressed the need for more high quality research to validate these technologies. "The standards would have to be set very high for new products, especially those intended for consumers," said FDA panelist Murad Alam, MD, a dermatologist from Northwestern University, Chicago, Illinois.

The panel also considered the FDA's proposal to change the classification status of Nevisense and any new products that assist dermatologists in melanoma detection from the most stringent regulatory category, class III, to the less restrictive class II. The Panel underscored the potential risks of reclassifying these technologies and strongly recommended keeping them in the class III category. SciBase shared the same opinion as panel experts through written submissions and oral presentations. SciBase believes the current process where FDA sets very high standards and is closely involved in clinical validation study design is the most appropriate.

"We very much agree with the Panel's recommendation. Nevisense is currently the only SLA available on the market and we have gone through the very rigorous Class III PMA (Pre Market Approval) process with it's extremely high safety demands. Reclassifying this type of product to Class II would reduce the level of FDA oversight for new products entering into this space; something we believe could potentially compromise patient safety.

While the FDA is not legally bound to follow the Panel's recommendation, we believe that such an overwhelming recommendation will be difficult for the FDA to ignore. A final decision from FDA could take months or years, though it is our belief that even in the medium term a decision would not practically affect Nevisense or the market itself as stringent requirements on clinical study data would still apply.", says Simon Grant CEO SciBase.

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About SciBase and Nevisense
SciBase is a global medical technology company headquartered in Stockholm, Sweden, that has developed a unique point of care platform for the non-invasive detection of skin cancer and other skin conditions. SciBase is a pioneer within augmented intelligence, combining artificial intelligence with Electrical Impedance Spectroscopy (EIS) to provide objective information that assists dermatologists and others in clinical decision-making. SciBase's products include Nevisense and Nevisense Go and to date the platform addresses the areas of melanoma detection, non-melanoma skin cancer detection and skin barrier assessment. Nevisense is the only FDA-approved device for the detection of melanoma and the only MDR-approved technology for skin cancer detection in Europe. SciBase's technology is based on more than 20 years of academic research at the Karolinska Institute in Stockholm, Sweden. For more information please visit www.scibase.com.