2015-08-31

SciBase's US Reader Study shows significant improvement in detection of melanoma using Nevisense

SciBase today announces the results from their Reader Study in the US. The results from the study show that the addition of Nevisense significantly improved the ability of US dermatologists to accurately detect melanoma. The Reader Study is an important requirement of the application process to the US Food and Drug Administration (FDA). With the results from the study, SciBase can now compile their complete application.

"We are very pleased with the result of the study. This was the last requirement from the US FDA for our Pre-Market Approval (PMA) application for Nevisense on the US market. Now that the Reader study is successfully completed, we can finalize and submit our application", says Simon Grant, CEO of SciBase.

41 US dermatologists reviewed online 141 randomly selected potential melanoma lesions; first with an image of each lesion together with patient information, and then with Nevisense information added.

The results showed that the use of Nevisense significantly improves physicians' ability to detect melanoma, whilst also satisfying the goal set for accuracy. This meant the study met both primary endpoints agreed with the FDA.

"The study results are in addition to the results from the SciBase pivotal study published last year, but with a different approach and with a broad group of US dermatologists. This shows that Nevisense has the potential to provide additional valuable information to clinicians in the difficult task of accurately detecting malignant melanomas", says Simon Grant, CEO of SciBase.

Approval from the FDA is required for SciBase to be able to market and sell Nevisense in the US, the world's largest medical device market. By meeting the FDA's requirements for the study, SciBase can now finalize its pre-market approval (PMA) application, which is scheduled for submission before the end of 2015.

SciBase's point-of-care device Nevisense is based on a method called Electrical Impedance Spectroscopy (EIS), which uses the varying electrical properties of human tissue to categorize cellular structures and thereby detect malignancies.

For more information, please contact:
Simon Grant, CEO
Phone: +46 72 887 43 99
Email: simon.grant@scibase.com

About SciBase and Nevisense

SciBase AB is a Swedish medical technology company, headquartered in Stockholm that has developed a unique point-of-care device for the accurate detection of malignant melanoma. Its product, Nevisense, helps doctors to detect malignant melanoma, the most dangerous type of skin cancer. SciBase was founded by Stig Ollmar, Associate Professor at The Karolinska Institute in Stockholm, Sweden. Nevisense is based on substantial research and has achieved excellent results in the largest clinical study ever conducted on the detection of malignant melanoma. Nevisense is CE marked in Europe, has TGA approval in Australia, and is awaiting FDA clearance in the United States. Nevisense is based on a method called Electrical Impedance Spectroscopy (EIS), which uses the varying electrical properties of human tissue to categorize cellular structures and thereby detect malignancies. SciBase is listed on Nasdaq First North ("SCIB"). Avanza is the certified advisor. Further information is available on www.scibase.com.