

PRESS RELEASE

Publication in British Journal of Dermatology validates the breakthrough Nevisense system as an accurate device for melanoma detection.

Stockholm, June 3, 2014 – SciBase AB, a leader in skin cancer detection technology, today announced the British Journal of Dermatology publication of a multi-centre international study for its unique point-of-care device, Nevisense. The results from the world's largest study of its kind show that Nevisense provides an accurate and important new tool for the detection of malignant melanoma, the most fatal form of skin cancer. Nevisense has already attracted widespread interest amongst dermatologists as the first non-visual melanoma detection system, using Electrical Impedance Spectroscopy (EIS) to objectively analyze lesions with suspicion of melanoma. SciBase believes the results of this eagerly anticipated study will lead to its widespread use in the often challenging process to accurately detect melanoma.

The multi-centre, prospective and blinded study was conducted at 5 US and 17 European investigational sites. A total of 1,951 subjects with 2,416 lesions were enrolled into the study; 1,943 lesions including 265 malignant melanomas were eligible and evaluable for the primary efficacy endpoint. Nevisense achieved a sensitivity of 97% with a specificity of 34% and the observed sensitivity for non-melanoma skin cancer was 100%.

Simon Grant, CEO SciBase, commented, "We are extremely excited about the results of this groundbreaking study. Detection of melanoma poses a challenge, especially in its earlier and most treatable stages. The study reflected this by evaluating the standalone performance of dermoscopy and histopathology, which showed sensitivities of 71% and 85% respectively. This confirms that Nevisense can detect melanomas potentially misdiagnosed using todays visual methods. The overall study results strongly indicate that Nevisense will improve the clinicians ability to detect melanoma in its earlier stages and thereby potentially save lives."

 Malvehy J, Hauschild A, Curiel-Lewandrowski C, et al. (2014). Clinical performance of the Nevisense system in cutaneous melanoma detection: an international, multi-centre, prospective and blinded clinical trial on efficacy and safety. British Journal of Dermatology.

Editor's Notes

About Skin Cancer

Skin cancer is one of the most common cancers in the world, accounting for nearly half of all cancers. It has been estimated that nearly half of all Americans who live to age 65 will develop skin cancer at least once. Malignant melanoma is the most fatal form of skin cancer causing the majority (75%) of deaths related to skin cancer. Worldwide, doctors diagnose about 160,000 new cases of melanoma yearly.

About Nevisense

Nevisense is a point-of-care device that has emerged from more than 20 years of academic research at both Karolinska Institutet Stockholm and SciBase. The device is designed to be used when a clinician chooses to obtain additional information when evaluating lesions with a suspicion of melanoma. Nevisense is based on a technology called Electrical Impedance Spectroscopy (EIS), which uses the varying electrical properties of human tissue to categorize cellular structures and thereby detect malignancies. The CE-marked system consists of an electrode on a hand-held probe connected to a small portable device performing the analysis and displaying the result

A video describing the Nevisense method is available on: www.scibase.se/en/the-nevisense-product

About SciBase

SciBase is a Swedish medical technology company founded in 1998 that has developed Nevisense, a device for the accurate detection of malignant melanoma. SciBase is actively marketing Nevisense in Germany, Australia and Nordic markets and will soon be providing it in further markets. A regulatory process for gaining approval on the US market is underway.

For more information, please visit www.scibase.se

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