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PRESS RELEASE

SciBase Announces Positive Top-Line Results from Pivotal Study

Excellent clinical study results for SciBase's unique product Nevisense in the largest prospective study ever conducted in the detection of Malignant Melanoma.

The Swedish medtech company, SciBase, today announced top-line results of its pivotal study SIMPS of Nevisense, a unique non-invasive point-of-care device for detection of Malignant Melanoma, the deadliest form of skin cancer. 22 clinics across Europe and the US participated in the blinded study which was conducted under an IDE approval from the FDA. The study included 2 400 skin lesions from 1 900 patients and 260 melanomas, making this the largest prospective study ever conducted in melanoma detection.

Nevisense achieved an overall sensitivity (the ability to accurately detect Malignant Melanoma) of 98% (lower confidence bound 95.5%) with 100% sensitivity on all stages of invasive melanomas. A specificity (the ability to accurately rule out Malignant Melanomas) of 33% (upper confidence bound 35.7%, lower confidence bound 30.4%) was achieved which is significantly higher than the study dermatologists. These results meet and exceed target study endpoints according to IDE-approval by the FDA. More detailed results will be presented pending full data analysis.

"We are very excited about these outstanding results", says Anders Lundqvist, CEO for SciBase AB. "Current visual methods for detection and diagnosis of malignant melanoma are highly subjective and uncertain. Nevisense's excellent outcome on sensitivity will allow for increased accuracy in diagnosis and saved lives by early detection. Dermatologists will now have access to a support tool providing them with additional valuable and objective information not previously available. Pathologists may also benefit from the objective Nevisense output, as the study results confirm that even pathology is far from 100% accurate. This means that patients risk not receiving correct diagnosis and adequate treatment. Last, but not least, a specificity higher than that of the physicians' paves the way for a dramatic reduction of performed biopsies and substantial health care savings."

Data from the pivotal study will provide the basis for the regulatory process for approval in the US as well as for market launch in Europe and Australia, all of which are planned for Q1 2013.

SciBase's method addresses the high uncertainty in melanoma detection
Malignant melanoma is the fastest growing form of cancer and, if not detected in time, the deadliest. Approximately 50-60 million visual inspections of suspicious lesions are performed annually world-wide. Despite an extensive amount of visual inspections, mortality rates are as high as 23%, which is the result of missed or late diagnosed melanomas. Early detection is critical for outcome and can be secured through extensive screening. However, today's method for detection, visual inspection, is subjective and uncertain which, besides the risk of missing melanoma, also results in a large amount of unnecessary excisions. Approximately 10-15% of screenings result in biopsies, whereof 95-97% represents biopsies of benign lesions.

SciBase provides a non-visual, accurate and objective method for the detection of malignant melanoma. The method, based on Electrical Impedance Spectroscopy (EIS), increases the physician's ability to identify suspected malignant melanoma, or rule out benign lesions. In addition to saving lives by early detection, the SciBase method can significantly reduce the time and money spent on unnecessary excisions as suspicious lesions can be scientifically evaluated already prior to excision.

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SciBase AB
SciBase AB is a Swedish medical technology company, founded in 1998. SciBase has developed a unique method and technology based on Electrical Impedance Spectroscopy (EIS). The patented method, emerging from academic research at Karolinska Institutet, Sweden, provides the ability for detection and monitoring of skin tissue alterations. The system consists of an electrode on a hand-held probe connected to a small device performing the analysis. Over 4 000 lesions have been clinically documented using the CE-marked device. Final product development and clinical verification is completed with clinical trial and the company is now looking to commercialise the product during Q1 2013 while in parallel initiated the regulatory approval process with the FDA.
For more information, please visit www.scibase.se