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PRESS RELEASE

## SciBase successfully achieves clinical study objectives

## Study targets met with SciBase unique method for first line detection of Malignant Melanoma

Swedish medtech company SciBase is in the final stage of development with its unique method for first line detection of malignant melanoma. A clinical study has recently been completed involving 1200 patients and 200 malignant melanomas from 19 clinical centers in Sweden, Germany, UK, Hungary and Switzerland. Study data shows that targets are met with sensitivity (the ability to detect malignant melanoma) exceeding 98% and specificity (the ability to rule out malignant melanoma) over 20% better than study dermatologists. More detailed results will be presented pending full data analysis.

Final clinical verification of the method's accuracy in the detection of malignant melanoma is currently ongoing through a pivotal study running at 23 centers across Europe and the US. An IDE (Investigational Device Exemption) approval for the study has been granted by the FDA, the regulatory authority in the US. Data from this study will provide the basis for market introduction in Europe and Australia as well as the regulatory process for approval in the US.

Malignant melanoma is the fastest growing form of cancer and, if not detected in time, the deadliest. 60-70 million visual inspections of suspicious moles are performed annually worldwide. Despite an extensive amount of visual inspections, mortality rates are as high as 25%, 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. Of 6-7 million excisions performed annually, only 3% are finally diagnosed as malignant melanoma.

SciBase will provide 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.

"We are extremely pleased with the outcome of the clinical study. With this result we have achieved a major milestone for the company and can now focus on the final clinical

verification study and preparation for the commercialisation which is scheduled for 2011" says Anders Lundqvist, CEO for SciBase AB.

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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 3000 lesions have been clinically documented using the CE-marked device. Final product development is completed with clinical trial training study finalized and pivotal verification study ongoing in Europe and US.

For more information, please visit www.scibase.se