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PRESS RELEASE

SciBase AB receives IDE approval from FDA

With this approval SciBase moves into final clinical stages with their unique method for first line detection of Malignant Melanoma

Swedish medtech company SciBase AB is moving into the final clinical stages with its unique method for first line detection & monitoring of Malignant Melanoma. Positive indications from the currently ongoing European multi-center training study show that the method is in line with the study target for sensitivity (the ability to detect melanoma). SciBase has now also received IDE (Investigational Device Exemption) approval from FDA for a pivotal study to be performed in Europe and the US in 2010 at up to 25 clinical institutions. The aim of the pivotal study is to provide final clinical verification of the method's accuracy in the detection of Malignant Melanoma. With this data, market introduction in Europe and Australia can be initiated in parallel to the regulatory process in US.

Malignant Melanoma is the fastest growing of all cancers and the most deadly cancer if not detected in time. Early detection is the most efficient tool to reduce mortalities. 60-70 million screenings for Malignant Melanoma are performed each year globally. Today's method for detection, visual inspection, is highly subjective and uncertain which, besides the risk of missing melanoma, also results in a large amount of unnecessary excisions.

SciBase will provide an accurate 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 surgeries as suspicious moles can be scientifically evaluated already prior to excision.

"It is with great confidence that we look forward to taking the method through the final clinical stages in anticipation of commercialisation in Europe and PMA submission for subsequent launch in the US" says Anders Lundqvist, CEO for SciBase AB.

For more information, please contact:

Anders Lundqvist, CEO SciBase AB, +46 732 06 98 08

Per Svedenhag, Director Clinical & Commercial Operations SciBase AB, +46 732 06 98 01

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 2000 lesions have been clinically documented using the CE-marked device. Final product development is completed with clinical trial training study in final stages and pivotal verification study to be performed in Europe and US during 2010 .

For more information, please visit www.scibase.se