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SciBase receives US approval for Nevisense

SciBase today announces that the US Food and Drug Administration (FDA) has approved the Scibase Pre-Market Approval (PMA) for its product Nevisense. Nevisense is SciBase's device for the early detection of malignant melanoma. With the approval, SciBase can now market and sell Nevisense in the US.

SciBase has now received confirmation from the FDA that the Nevisense PMA has been approved. According to the letter from the FDA the device is:

'intended for use on cutaneous lesions with one or more clinical or historical characteristics of melanoma, when a dermatologists chooses to obtain additional information when considering a biopsy.'

The approval means that SciBase now can start the commercial distribution and marketing of Nevisense on the US market. This means that Nevisense is now effectively the only device of its kind available on the US market for the detection of malignant melanoma.

- The Approval is a massive achievement and the result of eight years of hard work. The US Pre-Market Approval process is globally the most demanding regulatory process there is. As part of the Nevisense approval process SciBase were asked to perform the largest clinical trial of its kind ever performed within melanoma detection. The FDA also spent nearly a year reviewing SciBase's operations and processes. The approval is thereby a validation of us as a Company as well as of our product Nevisense.

Most employees in the company have been working directly or indirectly on the Approval for many years, and this really is a remarkable and nearly unique achievement given the size of our Company, says Simon Grant CEO SciBase.

For SciBase the approval means that the Company now can accelerate activities in preparation for the US introduction. The Company has been doing groundwork for some time and will present the strategy for the US introduction after summer.

- It's no secret that the US market is the world's largest and most profitable market for medical devices and in the long term, it represents a huge growth potential for us, says Simon Grant.

SciBase's device Nevisense is a tool to detect malignant melanoma directly on the skin. Skin cancer is the most common form of cancer and accounts for almost half of all cancer cases. There are estimates that show that half of all Americans that reaches 65 years of age will get skin cancer at least once during their lifetime. During 2017 over 87,000 Americans will be diagnosed with malignant melanoma. Malignant melanoma is the deadliest form of skin cancer and accounts for 75 percent of all the deaths related to skin cancer.

Briefly about the PMA-process
Pre-Market Approval (PMA) is the strictest process for approval for new medical devices in the US market and is required for most so-called Class III devices. Class III devices are often based on new methods that have previously not been approved by the FDA, which means that a number of clinical trials within the field needs to be performed over a long period. Development, clinical trials, preparation of the actual application and the process within the FDA has taken SciBase over eight years, which is normal. Due to the complex and resource demanding process it is only about 30 Companies annually that receive a PMA-approval. SciBase is one of only a handful of Swedish Companies that have successfully has completed a PMA-process.

A PMA application contains detailed information covering the device's development, manufacturing as well as the clinical trials that confirm the device's safety and effectiveness in use. In dialogue with the FDA, SciBase has developed and conducted the world's largest clinical study on detection of malignant melanoma as well as completed a so-called Reader study.

For further information please visit www.scibase.com or contact:
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This information is information that SciBase Holding AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 09.30 CET on June 29, 2017.

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 now also a 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.