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SciBase submits application for pre-market approval to FDA

The U.S. Food and Drug Administration (FDA) has confirmed that the organization has received SciBase's application for a pre-market approval (PMA) of the Nevisense device for the US market.

"We have been working with the clinical studies and documentation that the FDA requires for several years. It has been a long process that culminated in the completion of the application during this quarter. The US market is the world's largest and represents a significant opportunity for SciBase. Even a limited penetration of our method and Nevisense has the possibility to transform our business", says Simon Grant, CEO of SciBase.

The PMA is the FDA's most rigorous process for approval of new medical devices for the US market and is required for most so-called class III devices. Class III devices are usually based on a new method that has not yet been approved by the FDA. Due to the complex and resource-intensive process only about 30 companies apply for a PMA each year. If successful, SciBase will be one of only a handful of Swedish companies to complete 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. In addition, SciBase presented the results from a so-called Reader study during the third quarter. The Reader study was the final piece needed in order to complete the application.

The FDA is now starting the review of SciBase's PMA application. The company estimates that a decision from the FDA will be reached by the end of 2016, a more exact date is however hard to estimate.

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 230,000 new cases of melanoma yearly. The key to management is early detection, which is a challenge due to lack of objective tools for diagnosis, a problem that Nevisense addresses.

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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 is awaiting 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.