2016-01-20

SciBase's PMA application advances to evaluation phase at FDA

In December 2015 SciBase submitted its application for pre-market approval of its Nevisense device to the U.S. Food and Drug Administration (FDA). Scibase has now received confirmation that FDA considers that the application is complete and contains all necessary information to move on to the evaluation phase and start to review the application.

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 been approved by the FDA yet. Due to the complex and resource-intensive process only about 30 companies per year apply for a PMA. If successful, SciBase will be one of only a handful Swedish companies that have completed the PMA process.

"I have been through the PMA process before and know what it entails. Every step, such as the confirmation that our application is considered complete, takes us one step closer to our final goal of an approval. The FDA is now going to start the actual review of our application, which comprises several thousand pages", says Simon Grant, CEO of SciBase.

A PMA application contains detailed device information and demonstrates its safety and effectiveness in use. The application consists of the following components:

- Description of the device and the method
- Detailed history of development as well as manufacturing processes
- Detailed results of all conducted clinical studies, including among others SciBase's pivotal study, the largest study of its kind, as well as the Reader study conducted in 2015
- Information on documentation which is available to clients
- Summary of all evidence that shows that the product meets the FDA's requirements

Since the FDA confirmed that they received the application, SciBase has provided limited complementary information. The FDA now starts to review SciBase's PMA application and the company estimates that a decision from the FDA will be reached by the end of 2016. A more exact date is however difficult to estimate.

SciBase's device Nevisense is a tool to help doctors detect malignant melanoma. 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.