



SciBase Submits FDA 510(k) to Expand Nevisense into the Largest Skin Cancer Market

STOCKHOLM, Sweden – July 1, 2026 – SciBase Holding AB ("SciBase") [STO: SCIB] a leader in AI-based devices for detection and prevention in dermatology, today announced the submission of a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) seeking to expand the U.S. indication for Nevisense to include the assessment of Non-Melanoma Skin Cancers (keratinocyte skin cancers).

Nevisense is currently the only FDA-approved AI-driven technology in dermatology for the assessment and early detection of melanoma. If cleared, the expanded indication would extend the clinical utility of the existing Nevisense platform to include non-melanoma skin cancers, representing a significant expansion of its addressable U.S. market.

Non-Melanoma Skin Cancer Burden

More than 5.4^{1,2]} million cases of basal cell carcinoma and squamous cell carcinoma are diagnosed annually in the United States, making keratinocyte skin cancer the most common form of cancer. Delayed diagnosis can lead to, in the case of squamous cell carcinoma, metastatic disease, highlighting the need for objective technologies that support earlier clinical assessment and more informed biopsy decisions.

The submitted 510(k) premarket notification seeks to expand Nevisense's indication to include lesions with characteristics of keratinocyte skin cancer. In Europe, Nevisense is already CE marked for use in both melanoma and keratinocyte skin cancer, making the U.S. submission an important milestone in SciBase's strategy to broaden the clinical application of its technology.

"This submission represents an important milestone for SciBase and our strategy to expand the clinical applications of Nevisense in the United States," said Pia Renaudin, Chief Executive Officer of SciBase. "Keratinocyte skin cancer is estimated to be the most common form of cancer, and we believe Nevisense has the potential to provide dermatologists with objective decision support across an even broader range of suspicious skin lesions. Expanding Nevisense beyond melanoma represents an important step toward supporting clinicians across the broader spectrum of skin cancers encountered in daily dermatology practice. We look forward to working closely with the FDA throughout the review process."

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 below, at 08.30 CET on July 1, 2026.

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References

1. American Cancer Society. *Cancer Facts & Figures 2025*. [Melanoma incidence and ranking in the United States.]
2. American Academy of Dermatology. Approximately 5.4 million cases of basal cell carcinoma and squamous cell carcinoma are diagnosed annually in the United States.



About SciBase and Nevisense

SciBase is a global medical technology company, specializing in early detection and prevention in dermatology. SciBase develops and commercializes Nevisense, a unique point-of-care platform that combines AI (artificial intelligence) and advanced EIS technology to enhance diagnostic accuracy, ensuring proactive skin health management.

Our commitment is to minimize patient suffering, allowing clinicians to improve and save lives through timely detection and intervention and reduce healthcare costs.

Built on more than 20 years of research at Karolinska Institute in Stockholm, Sweden, SciBase is a leader in dermatological advancements.

The company has been on the Nasdaq First North Growth Market exchange since June 2, 2015 and the company's Certified Adviser is DNB Carnegie Investment Bank AB (publ). Learn more at www.scibase.com. For press releases and financial reports visit: <http://investors.scibase.se/en/pressreleases>
