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SciBase receives FDA approval for Nevisense 3.0

SciBase (SCIB) Stockholm, Sweden - announces today that it has received approval from the US Food and Drug Administration (FDA) for Nevisense 3.0, the third generation of their Nevisense system for early melanoma detection. Nevisense, an AI-based point-of-care system for the non-invasive evaluation of irregular moles remains the only FDA approved system available for melanoma detection in the US.

Nevisense 3.0 is a more efficient and streamlined version of the product previously approved by the FDA. The European version released at the end of 2018 has significantly improved both adoption and utilization, and has been used clinically on over 30,000 patients to date.

"The release of Nevisense 3.0 in late 2018 in Germany and the EU has been the catalyst for five consecutive quarters of growth, and we see this as step one of our strategic plan" said Simon Grant, Chief Executive Officer of SciBase. "Receiving US approval means that we can focus on step two of our strategy which is to increase our marketing and sales activities in the US based on our deep market experience with Nevisense 3.0 in Germany and the positioning we have developed for Nevisense in the US.'

For more information, please contact:
Simon Grant, CEO SciBase
Tel: +46 72 887 43 99
Email: simon.grant@scibase.com

Certified Advisor (CA):
Avanza
Tel: +46 8 409 421 20
Email: corp@avanza.se

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 12.45 CET on May 1, 2020.

About SciBase and Nevisense

SciBase AB is a Swedish medical technology company, headquartered in Stockholm that has developed and sells a unique point-of-care device for evaluation of skin disorders such as skin cancer and atopic dermatitis. Its first product, Nevisense, helps doctors to detect malignant melanoma, the most dangerous type of skin cancer. Further development has led to Nevisense also being used as a tool to assess the skin barrier and inflammation. 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 an FDA approval (PMA) 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 and abnormalities. SciBase is listed on First North Growth Market ("SCIB"). Further information is available at www.scibase.com.