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New data from NeoDynamics' PULSE study presented at major US breast imaging conference

Data from the NeoDynamics' PULSE study with its biopsy device NeoNavia shows a success rate of 96% in very complex and risky axilla biopsies. The new data was presented by Professor Marc Thill at the SBI/ACR Breast Imaging Symposium in Savannah, Georgia.

The conference, taking place on May 16-19, is held to be the most important annual meeting for US breast imaging professionals. That the new data was selected for oral presentation at the US conference indicates a strong interest in the results among breast biopsy specialists. The study illustrates the significant contribution NeoNavia can provide, particularly in difficult and complex breast and axilla biopsies.

"In the PULSE study we described characteristics of each axillary biopsy case in a detailed way. Fifty patients in the interim data set showed parameters indicating a challenging procedure such as close distance of the lymph node to a blood vessel, thoracic wall, or muscle. A separate analysis in this sub-group showed a procedure success rate of 96% and low rate of adverse events with only one minor hematoma and two cases of pain, none of which required further treatment. The users reported that pulses facilitated control during needle insertion in 94% of cases and stabilization of the target lesion during needle insertion in 92% of cases. The reported results in these challenging cases further underline the strong performance of the NeoNavia device," says **Prof. Marc Thill** who presented the results at the first day of the Conference.

The PULSE study is an ethically approved German prospective multi-center study (ClinicalTrials.gov ID: NCT03975855) designed to document the performance of the NeoNavia biopsy device in the axillary lymph nodes. NeoDynamics have previously reported data from 115 procedures showing that the device is well suited for the use in the axillary lymph nodes, with a high success rate and low rate of adverse events in a broad patient group.

NeoNavia is an innovative biopsy system built on a patented pulse technology for controlled and precise needle insertion, and is based on research at the Karolinska Institutet in Sweden. The system was developed by NeoDynamics and is being commercially introduced in selected markets in Europe. NeoDynamics recently filed a registration application for NeoNavia in the USA.

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About NeoDynamics

NeoDynamics AB (publ) is a Swedish Medical Technology Company dedicated to advancing diagnosis and care of breast cancer. The company's first product NeoNavia®, a new innovative pulse biopsy system for ultrasound guided tissue sampling, is currently being introduced to the market. The biopsy system is built on a patented pulse technology, based on research at the Karolinska Institutet in Sweden. NeoNavia is evaluated for breast cancer diagnosis at leading clinics in UK, Germany, and Sweden. The pulse biopsy system has been used for tissue sampling in breast and axilla in over 500 patients.

About NeoNavia

NeoNavia is a modern biopsy system with a completely new patented pulse technology intended for ultrasound-guided tissue sampling. It consists of a base unit, a handheld driver and three different types of biopsy needles. Each needle type is driven by the pulse technology providing a more controlled needle insertion and precise placement of the needle in the tumour whilst enabling high-quality tissue samples from both breasts and lymph nodes. The pulse biopsy system NeoNavia is designed to offer clinicians and patients accurate lesion targeting and high tissue yield for correct diagnosis and individualized treatment.