

Final data set from NeoDynamics' PULSE study presented at The SBI Breast Imaging Symposium

The final data set from NeoDynamics' PULSE study shows favorable safety and efficacy profile of NeoNavia for ultra-sound guided biopsies in the axillary lymph nodes. The data are being presented at The SBI Breast Imaging Symposium this week.

The conference, taking place on May 4-7 2023, at the Gaylord National Resort & Convention Center in National Harbor, Maryland, is the World's Largest Breast Imaging Conference.

NeoDynamics' PULSE study is a German prospective multi-center study (ClinicalTrials.gov ID: NCT03975855) designed to document the performance of the NeoNavia biopsy device in the axillary lymph nodes on 138 enrolled patients. Professor Marc Thill, PhD, has been principal investigator. An electronic presentation of his abstract is presented at the Symposium.

The key data of the finalized study are:

- Success rate for biopsies from the lymph node was 93 % (128/138). ("high success rate")
- Hematoma in the axilla occurred in 1.4% (2/138) of patients. Pain in the axilla was reported in 2.9 % (4/138) of patients. ("low rate of adverse events")
- The pneumatic pulses promoted control during needle insertion in 89% (123/138) and stabilization of target lesion during needle insertion in 88% (122/138) of patients.
- 46% (64/138) of patients presented with at least one of four major risk parameters (lymph node diameter <10mm, proximity to blood vessel/muscle/thoracic wall <5mm) ("broad patient cohort")

The study has demonstrated that pneumatic pulses promoted needle control and stabilization of target lesions during insertion of the needle and that it was possible to obtain multiple samples with a single insertion.

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About NeoDynamics

NeoDynamics AB is a Swedish Medical Technology Company dedicated to advancing diagnosis and care of 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 Europe and launches in USA during 2023. NeoDynamic's shares are listed on Nasdaq First North Growth Market Stockholm (ticker: NEOD). The company's Certified Adviser is Redeye AB.

About NeoNavia

NeoNavia is a modern biopsy system with a completely new patented pulse technology intended for ultrasound-guided tissue sampling. Each needle type is driven by the pulse technology providing a more controlled needle insertion and precise placement of the needle in the tumor 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.

About Karolinska Institute

The Karolinska Institute is consistently ranked amongst the world's best medical schools, ranking 6th worldwide for medicine in 2021. The Nobel Assembly at the Karolinska Institute awards the Nobel Prize in Physiology or Medicine.

Attachments

[Final data set from NeoDynamics' PULSE study presented at The SBI Breast Imaging Symposium](#)