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NeoDynamics launches device registry in Germany, costeffective collection of real-world data

NeoDynamics is proud to announce the launch of a device registry in Germany for its NeoNavia Biopsy System. The registry, which has recently seen the first procedure documented, is a key initiative in collecting real-world data and will be rolled out to several hospitals across Germany This effort not only demonstrates our commitment to cost efficiency but also supports compliance with the stringent post-market surveillance requirements mandated by the Medical Device Regulation (MDR).

The NeoNavia Biopsy System, renowned for its precision and precision in biopsy procedures, will now be further evaluated through real-world data collected from this registry. This data will encompass all three needle types used in the system, providing a comprehensive understanding of its performance across various clinical scenarios.

Conventional clinical studies, while comprehensive, often involve significant resources and expenses. By adopting a registry-based approach, NeoDynamics embraces a more sustainable method for continuous data collection.

Dr. Kai-Uwe Schässburger, Director of Clinical Development and Medical Affairs at NeoDynamics, emphasized the strategic importance of the registry, stating, 'This initiative not only showcases our commitment to cost-efficient solutions to comply with regulatory requirement but also positions us to leverage the collected real-world data for impactful medical communication."

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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.

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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

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