NeoDynamics receives regulatory approval for new breast cancer biopsy system

NeoDynamics today received confirmation from Intertek (Notified Body) that the improved version of the new system for breast cancer biopsy, NeoNavia, is accepted as an update to the already EU approved study version. The upgraded pulse biopsy system including three needle types, is added to the product list on the company's EC certificate.

The confirmation that Intertek has accepted the new improved version as an update to the already EU approved system used in clinical trials in Germany, UK and Sweden, eliminates uncertainty and significantly shortens time to market.

The EC certificate permits NeoDynamics to CE-mark the new products as soon as the company's procedures for CE-marking are fulfilled.

"The regulatory approval is a major milestone for NeoDynamics. We can now fully focus on finalizing formal verification and validation of the updated system while accelerating all remaining activities before the planned launch mid-2020", says Anna Eriksrud, CEO NeoDynamics**. "**The introduction of NeoNavia has the potential to set a new standard for precision biopsy in breast cancer".

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This information is information that NeoDynamics AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication by the contact person above on 29 October, 2019

About NeoDynamics

NeoDynamics AB (publ) is a Swedish Medical Technology Company dedicated to advancing diagnosis and care of breast cancer. The company has an innovative biopsy system, NeoNavia® , in late stage development. The precision biopsy system is built on a patented micro-pulse technology, based on research at the Karolinska Institutet in Sweden. The system is designed to offer clinicians and patients accurate lesion targeting and high tissue yield for correct diagnosis and individualized treatment. NeoNavia® is evaluated at leading clinics in UK, Germany and Sweden. A commercial launch is expected in 2020.

About NeoNavia

NeoNavia is the brand name for the entire biopsy system intended to be used under ultrasound guidance. NeoNavia consists of a base unit, a handheld driver and three different types of biopsy needles. Each needle type is driven by the micro-pulses enabling high precision and control when inserting and positioning the biopsy needle in a suspicious lesion. The system is designed to offer accurate lesion targeting and high tissue yield for correct diagnosis and individualized treatment.

About the micro-pulse technology

The patented micro-pulse technology is based on a pneumatically driven mechanism that enables high precision and control when inserting and positioning the biopsy needle, independent of tissue type. The pneumatic driver that generates micro-pulses is placed in a handheld instrument. With power from the base-unit, the driver accelerates the needle with great control even over a short distance, enabling its distinct stepwise insertion without the risk of destroying surrounding tissue. This facilitates ease of access and flexibility in sampling, even in very small lesions in delicate and difficult locations.