

## New technology from NeoDynamics approved for study in Germany

### German multi-center study ("PULSE") receives ethical approval and endorsement of the German Society of Gynecology and Obstetrics

–“Together with my colleagues from other university hospitals we have collaborated with NeoDynamics during the last couple of years in the development of the NeoNavia biopsy system. Innovation in this field has been scarce and thus the interest for new technology among clinicians is high. The developed technology has unique characteristics which enable a more precise and controllable needle insertion, something that is an advantage in all procedures but especially in those that are considered challenging. After initial positive experience in our hospital we now want to take the next step and commence with the PULSE study”, says Priv.-Doz. Dr. med. Marc Thill of the Agaplesion Markuskrankenhaus in Frankfurt and leading Principal Investigator.

Performing needle biopsies in axillary lymph nodes poses specific challenging with regards to precision and control. The micropulse technology incorporated in NeoNavia is based on a pneumatic driver that enables a user-controlled stepwise needle insertion without noticeable deformation or displacement of surrounding tissue. In Addition, a new needle design facilitates maximum sampling yield with minimal patient trauma.

The PULSE study has been designed together with leading German physicians to demonstrate performance characteristics of the NeoNavia biopsy system for biopsies in the axillary lymph nodes.

The PULSE study has now received ethical approval and patient recruitment for this prospective multi-center study is planned to start in November at the Agaplesion Markuskrankenhaus in Frankfurt. At least seven additional university hospitals in Munich, Berlin, Rostock, Greifswald, Tübingen, Esslingen and Essen will successively join the clinical study team.

Furthermore, the working group of esthetic, plastic and reconstructive surgical interventions (the AWOgyn e.V.) of the German Society of Gynecology and Obstetrics (DGGG) has included PULSE into their clinical study portfolio. This provides access to the group's infrastructure and regular exposure at scientific meetings.

– “We are happy to get started with the PULSE-study and continue to demonstrate what our technology is capable of. With Dr. Thill we have a high profile Principal Investigator on board with vast experience in evaluating new medical technology. We are especially proud of the endorsement by the DGGG which shows that we pursue ideas of clinical relevance and ensures support of the medical community”, says Kai-Uwe Schässburger, Director of Clinical Development and Medical Affairs at NeoDynamics.

### About NeoDynamics

Every year, approximately 2.1 million women worldwide are diagnosed with breast cancer, increasing by five percent per year. NeoDynamics has developed the NeoNavia® biopsy system which facilitates and improves tissue sampling (biopsies) in breast cancer patients, with a new patented micropulse technology. This method gives better precision and better control. In close collaboration with leading clinicians, NeoDynamics have gained experience of having used the technology in more than 300 procedures at around 15 university hospitals across Europe. NeoDynamics is currently completing the development of the commercial version of NeoNavia. Together with several design and usability features it integrates micropulse technology with multiple needle options to provide maximum flexibility. NeoNavia is expected to be launched towards the end of 2019 in a breast biopsy market worth approximately USD 500 million per year. The technology is also considered suitable for cancer diagnostics in other organs such as prostate, lung, kidney and liver.

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### Facts about

#### Micropulse technology

The micropulse technology is based on pressurized air generated by a compressor driving the mechanism located in the handheld driver. A pneumatic insertion mechanism enables precise and user controlled needle insertion regardless of tissue characteristics. Stepwise needle insertion without noticeable deformation or displacement of surrounding tissue is achieved as visualized under ultrasound.

#### NeoNavia®

NeoNavia biopsy system is composed of a base unit and a biopsy device, and is operated together with ultrasound imaging guidance. The base unit supplies the biopsy device with power and controls the operation during the biopsy procedure. The current sampling needle is designed to facilitate maximum sampling yield with minimal tissue trauma. This makes the NeoNavia system particularly well suited for ensuring safe and precise sampling of technically challenging lesions. These might be lesions difficult to reach or target, lesions near delicate anatomical structures, and lesions that are easily displaced by the biopsy needle tip, resulting in the collection of non-representative samples.

Currently NeoNavia exists in a CE-marked study version and since late 2016 it has been tested by leading specialists at some 15 cancer centers in Europe, evaluating both the micropulse technology and NeoNavia's needle. More than 300 patients have undergone breast and axillary lymph node biopsies with this new micropulse technology and a clinical study is currently ongoing in Germany to further establish the technology. These evaluations and tests have been vital for the development of the enhanced NeoNavia biopsy system planned for commercial launch late 2019.