Press Release
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NanoEcho submits application to the authority to start a clinical study

NanoEcho AB (publ), which develops a new diagnostic method to investigate the spread of rectal cancer to nearby lymph nodes, has today submitted an application to the Swedish Medicines Agency to evaluate the company's medical diagnostic device in a clinical study. In the planned study, NanoEcho's method will be used and evaluated on patients with rectal cancer.

In June 2024, NanoEcho completed the product development of its commercial imaging device, following the successful finalisation of formal verification. This means that the device is safe, reliable and approved for use on patients in clinical studies. The application to the Swedish Medicines Agency has now been submitted to initiate the clinical study.

The clinical study, to which the application relates, is planned to be carried out in two stages. Initially, the suitable dose of the nanoparticles and time of examination will be identified on healthy volunteers. Secondly, "Proof of Concept" will be initiated on patients with rectal cancer. The goal, of this part of the study, is to show that the selected dose and time of the examination is suitable on patients with rectal cancer. Once the authority has approved the application, the clinical study can commence.

> “We have worked intensively with a team of experts with clinical and regulatory expertise to compile our application. Now everything is in place and we are very satisfied with the clinical protocol and the application we sent in today," says Ulrika Axelsson, Clinical Director at NanoEcho.

> "We are now taking another significant step towards meeting the great unmet need for reliable diagnostics for patients with rectal cancer. In the planned study, our method will be used and evaluated on patients with rectal cancer for the first time. The application marks an important milestone towards a market launch and I am incredibly proud of the progress we have made that has led us to where we are today", says Linda Persson, CEO of NanoEcho.

Once this study has been completed, a registration study is planned to be conducted. The goal is to create the basis for market approval of the imaging system, which includes both equipment and nanoparticles. The plan is to complete the registration study and apply for market approval from the authorities during 2027. This plan is based on the company being able to raise the necessary capital.

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NanoEcho develops a new technology for clearer diagnostics of, in the first indication, rectal cancer. The imaging technology is based on a new medical approach where nanotechnology is used in combination with modern patented ultrasound technology. The images that are generated are intended to facilitate differentiation between healthy and diseased tissue and at the same time determine the location of the cancer tissue more precisely. The goal is to provide a more reliable diagnosis of, for example cancer diseases, that has the potential to contribute to cost-effectiveness in health care. **www.nanoecho.se**