

## PRESS RELEASE

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# Distinct images in clinical study with SpagoPix

**Interim results from the phase I study SPAGOPIX-01 show that SN132D provides MRI contrast enhancement in breast tumors. In line with previous preclinical data the clinical results confirm accumulation of the unique nanomaterial in solid tumors. In addition, unexpectedly good contrast in the pancreas has been observed in all images from the study so far, representing an opportunity the company will explore further.**

Spago Nanomedical CEO Mats Hansen will provide comments on the results in a webcast, today at 1 pm, which can be reached by the following link: <https://www.finwire.tv/webcast/spago-nanomedical/q3/>.

The interim results refer to the second dose group in the study SPAGOPIX-01, where patients with breast cancer for the first time received a dose that was expected to be sufficient to result in clinically meaningful contrast. A clear contrast enhancement was observed in breast tumors on the MR-images from the dose group. This indicates that SN132D may facilitate future investigation and monitoring of suspected and diagnosed breast cancer with MRI.

The observed results are the first to clearly show that Spago Nanomedicals nanoparticles accumulate in human tumors. The accumulation is based on physiological targeting, which is also used in the company's project Tumorad® which aims to develop a precision treatment of several different cancers.

The principle of physiological targeting is based on the nature of the blood vessels in tumors and is termed the EPR effect (Enhanced Permeability and Retention). By this effect, nanomaterials can be designed to accumulate in tumors without having to interact biologically with the tumor cells. This opens the door to address different types of tumors with greater precision and for the diagnosis and treatment of aggressive and spread cancer.

"The results are very promising, of course for SpagoPix, but also for Tumorad®, as both projects are based on physiological targeting with our platform material. With Tumorad® we aim for precision treatment by irradiation of tumors inside the body," says CEO Mats Hansen.

The safety data generated so far in the study does not provide reason for any changes in the study protocol. The study now proceeds with inclusion of additional patients at the same dose level to expand the data base and provide guidance for future clinical studies required for market approval. The recruitment rate in the study has been negatively affected by the pandemic, but an increasing patient flow has been noted after the summer. Spago Nanomedical estimates that the study can be completed at current study sites within a reasonable time.

In addition to the positive contrast enhancement in breast tumors, all MRI images in the study, including both dose groups, show a very good contrast in the pancreas. This positive and unexpected result has prompted Spago Nanomedical to investigate the potential of SpagoPix as an MRI contrast agent in this area as well. Initial discussions with radiologists in Europe and the United States suggest there is a pronounced medical need for identification and follow-up of patients with various forms of potentially pre-cancerous lesions or cysts in this organ.

"Our main focus remains on breast cancer, but the images we got of pancreas are striking and we see an opportunity for indication expansion by using SN132D to improve the detection and treatment of patients with potentially serious changes in the pancreas," says Mats Hansen.

SpagoPix (SN132D) is a contrast agent with the potential to significantly improve cancer diagnosis with magnetic resonance imaging (MRI). Spago Nanomedical has initially chosen to focus on breast cancer, a disease that annually affects about 2.1 million people, and where MRI is already routinely used for screening, diagnosis, or follow-up in 15-30 percent of all patients and the need for better precision in diagnoses is large. The market potential for improved MRI for breast cancer patients is estimated to be up to approx. 10 billion SEK annually.

Based on the annual mortality rates related to aggressive or metastatic cancer in indications with a documented EPR effect, and a market price in line with current treatments, the market potential for Tumorad® is estimated at 15-40 billion SEK annually.

The primary endpoint of the SPAGOPIX-01 study is to document safety at different dose levels, but an important secondary endpoint is to investigate MRI contrast in patients with confirmed breast cancer. Study details and updates are published at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

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*Spago Nanomedical AB is a Swedish nanomedicines company in clinical development phase. The company's development projects are based on a platform of polymeric materials with unique properties for more precise diagnosis and treatment of solid tumors. Spago Nanomedical's share is listed on Spotlight Stock Market in Stockholm (ticker: SPAG). For further information, see [www.spagonanomedical.se](http://www.spagonanomedical.se).*

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