

## PRESS RELEASE

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# Spago Nanomedicals phase 1 study with SpagoPix shows clear contrast enhancement and is expanded into new indications

Spago Nanomedical AB (publ) today announced that interim results from the second dose group in the company's ongoing clinical phase I study SPAGOPIX-01 show that SpagoPix (SN132D) is well tolerated and provides clear contrast enhancement in MRI images of solid tumors in the breast, as well as in the pancreas and liver. Based on the results, the company has decided to continue the study in breast cancer and in addition, to expand to also include patients with pancreatic and liver cancer.

A total of 12 patients with confirmed breast cancer have been included in the phase I study SPAGOPIX-01 with the tumor-selective contrast agent SpagoPix (SN132D). After analyzing the data, the internal safety committee for the study has concluded that SN132D is safe at the second, higher dose level.

The MRI images from the 6 patients in the second dose group show that SN132D provides clear contrast enhancement in breast tumors as well as in the pancreas and liver. The results thus confirm previously presented interim results that SN132D accumulates in solid tumors.

"It is very gratifying that we, once again, can show that our contrast agent SN132D clearly accumulates in cancerous tumors and provide images that with both high precision and positive contrast show the tumor against a clean background. Fortified by these positive results, together with previously presented data, we are continuing the project at full speed, both in breast cancer and in new indications with large clinical need," said CEO Mats Hansen.

The primary endpoint of the study is to study safety at different doses of SN132D. Secondary endpoints include how the contrast agent can enhance MRI images in clinical use in patients with solid breast tumors, and how the contrast agent can enhance MRI images of the pancreas and liver. Based on analysis of the interim results, the company will continue evaluating SN132D in breast cancer and has decided to broaden the indication area to include patients with documented pancreatic cancer with metastases in the liver. An application for an amendment to the current study protocol is being submitted to the Swedish Medical Products Agency. Spago Nanomedical is also evaluating SN132D in additional indications areas of clinical need.

The interim results presented so far show that Spago Nanomedical's platform technology makes it possible to clinically and precisely accumulate functional nanoparticles in solid tumors. This is also of great importance for the company's project Tumorad®, which aims to develop a precision treatment for several different cancers. Tumorad, with the candidate drug code SN201, has demonstrated a positive effect by slowing tumor growth in a preclinical model for aggressive breast cancer. Further preclinical studies in other cancer models are ongoing.

"Since the Tumorad project is based on the same technology and principle as SpagoPix, i.e. to get nanomaterials to accumulate in tumors without having to interact biologically with the tumor cells, the results are also important for the continued development of Tumorad. In parallel with the continued evaluation of SpagoPix, we plan to start the first study in humans with SN201 in 2022," said Mats Hansen.

SN132D is a contrast agent with the potential to significantly improve cancer diagnosis with magnetic resonance imaging (MRI). Spago Nanomedical has initially selected to focus on breast cancer, a disease that annually affects about 2.1 million people, where MRI is already routinely used for screening, diagnosis, or follow-up in 15-30 percent of all patients, and where there is a large need for improved precision in diagnoses. Pancreatic cancer is one of the deadliest cancers and leads to more than 400,000 deaths worldwide each year. The need for improved diagnostic methods is also great, especially as there is currently a lack of effective imaging diagnostics to guide the treatment for the spread of the disease to the liver.

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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 Nasdaq First North Growth Market (ticker: SPAGO). For further information, see [www.spagonanomedical.se](http://www.spagonanomedical.se).*

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