

PRESS RELEASE

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SpagoPix phase I study to next dose level and expansion to additional site

Data from the first dose group in the phase I trial show that SN132D is well tolerated, and provide valuable information for optimization of MRI in the next step. Now that the study continues into the next dose level the company intend to up the pace in patient recruitment by engaging an additional study center.

The internal safety review committee (iSRC) has analysed data of the first six patients of the clinical study SPAGOPIX-01 and concluded that the initial dose of SN132D is safe. The iSRC further conclude that the dose should be increased in order to optimize contrast enhancement of tumors. The study now continues with the next group of patients, data from this group will be subject for a new interim analysis.

The fact that the first dose-cohort has been successfully completed is expected to facilitate the continued patient recruitment. In order to increase the addressable patient population and further increase the recruitment tempo, Spago Nanomedical has decided to expand the study to an additional breast cancer center, Sahlgrenska University Hospital.

"The results are completely in line with our expectations and we are now looking forward to results from the next dose level. We also intend to expand the trial to an additional study center in order to broaden the recruitment base and facilitate the study inclusion tempo", says Spago Nanomedical CEO Mats Hansen.

The study dose of SN132D that patients has been given up to now has a broad safety margin to levels where safety signs has been demonstrated in preclinical studies. The objective with the initial dose was to document initial safety and provide basis for optimization of the imaging protocol for the following dose levels.

SpagoPix (SN132D) is a tumor selective and gadolinium-free contrast agent with potential to significantly improve the diagnosis of solid tumors with magnetic resonance imaging (MRI). Spago Nanomedical's focus is initially on imaging of breast cancer, a disease that affects approximately 2.1 million people annually. MRI is routinely used for screening, diagnosis, and follow-up in 15-30% of all breast cancer patients but the need for better diagnostic precision is substantial.

The primary objective of SPAGOPIX-01 is to evaluate safety at escalating doses in up to 20 patients with confirmed breast cancer. Another important objective is to investigate clinical MRI contrast enhancement of SN132D in this group of patients.

Study details and updates are published at 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.

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