

PRESS RELEASE

Lund, Sweden, December 18, 2024

Second patient group successfully dosed in Spago Nanomedical's Phase I/IIa study Tumorad-01

Spago Nanomedical AB (publ) today announced that all patients in the second patient group have been dosed according to plan in the company's Phase I/IIa study Tumorad-01 with the candidate drug 177Lu-SN201. The study's independent Data Monitoring Committee (DMC) is expected to be able to present its analysis of the patient group during the first quarter. A total of six patients have so far been included and dosed in the study.

The Phase I/IIa clinical study Tumorad-01 is a first-in-human study with the primary purpose of evaluating the safety, tolerability, dosimetry and initial efficacy of 177Lu-SN201 in cancer patients. The Phase I part of the study aims to identify a possible therapeutic dose for further testing in selected patient groups in the Phase IIa part of the study. In August 2024, the company announced that the first patient group in the Phase I part of the study, consisting of three patients, had been successfully treated with at least one dose of 177Lu-SN201. Furthermore, the DMC recommended that the study continue based on an evaluation of all available data. Now the second patient group in the study, consisting of three patients, two men with lung and rectal cancer and one woman with throat cancer, has also been treated with at least one dose/cycle of 177Lu-SN201. The next evaluation by the DMC is thus expected to be presented during the first quarter. In the meantime, recruitment of patients to the study continues.

"It is gratifying that the study is proceeding according to plan and we are now awaiting the DMC's analysis of this second group of patients early next year. We are pleased with the inclusion so far of patients with a total of five different cancers, which provides the conditions to evaluate the candidate drug in different tumor types at an early stage," says CEO Mats Hansen.

Clinical evidence for selective tumor accumulation of Spago Nanomedical's functional nanoparticles has previously been generated with the MRI contrast agent pegfosimer manganese (SN132D) in breast cancer patients. The candidate drug in Tumorad, 177Lu-SN201, is based on the same type of carefully optimized polymeric nanomaterials combined with the clinically effective radioisotope lutetium-177 (177Lu), which is already used in market-approved drugs. This makes 177Lu-SN201 a promising new radioisotope drug for tumor-selective treatment of cancer with possible use against more tumors types compared to existing radionuclide therapies. If a favorable biodistribution of radiation to tumors compared to other organs can be demonstrated, 177Lu-SN201 has the potential to become an effective drug against cancer.

More information about the Tumorad-01 study is available at <https://clinicaltrials.gov/study/NCT06184035>

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Spago Nanomedical AB is a Swedish company in clinical development phase. The company's development projects are based on a platform of polymeric materials with unique properties for more precise treatment and diagnosis of cancer and other debilitating diseases. Spago Nanomedical's share is listed on Nasdaq First North Growth Market (ticker: SPAGO). For further information, see www.spagonanomedical.se.

FNCA Sweden AB is the Certified Adviser of the company.

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