

PRESS RELEASE

Lund, Sweden, December 7, 2023

First patient dosed in Spago Nanomedical's clinical phase I/IIa study within the Tumorad® program

Spago Nanomedical AB (publ) announced today that the first cancer patient has successfully been dosed in the clinical phase I/IIa study Tumorad-01 with the candidate drug 177Lu-SN201. Initial data regarding safety and biodistribution from the phase I part of the study is expected to be reported already in the first half of 2024.

Tumorad-01 is a phase I/IIa first-in-human study in patients with advanced cancer with the primary objective of evaluating safety, tolerability, dosimetry and initial efficacy of 177Lu-SN201. The phase I part of the study is designed for up to 30 cancer patients and aims to, based on safety and biodistribution, identify a possible therapeutic dose for further testing in selected patient groups in the phase IIa part of the study.

"We are pleased to see that the first patient with advanced cancer has now been successfully dosed in this first in human study within the Tumorad program. With an open study design that allows for continuous data reporting, we expect initial data demonstrating the biodistribution and accumulation of 177Lu-SN201 in tumors in cancer patients early in the study. These data are of great importance as they can give an indication of the utility of the compound in cancer patients," says CEO Mats Hansen.

The study is initially run at a number of clinics in Australia and as the study progresses, clinics in other countries may also be included.

Study details will be published at www.clinicaltrials.gov.

Clinical evidence of selective tumor accumulation of Spago Nanomedical's functional nanoparticles has previously been generated with the MRI contrast agent SN132D in breast cancer patients. In the Tumorad candidate drug 177Lu-SN201, the same type of carefully optimized polymeric nanomaterial is combined with the effective radioisotope lutetium-177 (177Lu), which was previously used in market approved drugs. This makes 177Lu-SN201 a promising new radionuclide therapy for tumor-selective treatment of cancer with potential use in multiple tumor types.

The Tumorad-01 study is designed to enable early data demonstrating safety, biodistribution and accumulation of 177Lu-SN201 in tumors in cancer patients. With a favorable distribution of radiation to tumors compared to other organs, 177Lu-SN201 has good potential to become an effective drug against cancer.

For further information, please contact Mats Hansen, CEO Spago Nanomedical AB, +46 46 811 88, mats.hansen@spagonanomedical.se



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.

This information is information that Spago Nanomedical is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-12-07 07:09 CET.

First patient dosed in Spago Nanomedical's clinical phase I/IIa study within the Tumorad® program