

PRESS RELEASE

Lund, Sweden, May 20, 2024

Spago Nanomedical provides an update on Tumorad-01 – trial proceeds as planned

Spago Nanomedical AB (publ) announced today that both of the clinical sites in the phase I/IIa study Tumorad-01 are actively recruiting patients. So far two patients have been enrolled and successfully dosed. A third patient is enrolled and awaits treatment, with a fourth patient also identified. The study continues according to plan, with focus on recruiting patients with different tumor types.

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 the candidate drug ¹⁷⁷Lu-SN201. The phase I part of the study 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.

Two patients have successfully completed initial dosing of 10 MBq/kg, both males with metastatic castration-resistant prostate cancer (mCRPC). So far, no serious adverse events (SAEs) have been reported. Patients 3 and 4 are female with different tumor types.

The next Data Monitoring Committee (DMC) meeting is expected after all three patients in the first cohort have completed the first treatment cycle. The DMC will evaluate all available safety, pharmacokinetics, biodistribution, and dosimetry data and the company aim to provide an update on the first study data following this evaluation remains.

“We are pleased with the progression of this first in human study within the Tumorad program. The sites in Australia show great commitment and are actively recruiting patients. We look forward to the DMC’s evaluation and recommendation following completion of the initial patient cohort according to the study protocol. Our main focus is to further progress the study according to the protocol’s objectives by recruiting patients with different tumor types” says CEO Mats Hansen.

Clinical evidence of 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. In the Tumorad candidate drug ¹⁷⁷Lu-SN201, the same type of carefully optimized polymeric nanomaterial is combined with the clinically effective radioisotope lutetium-177 (¹⁷⁷Lu), which is already 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. If a favorable biodistribution of radiation to tumors compared to other organs can be demonstrated, ¹⁷⁷Lu-SN201 has good potential to become an effective drug against cancer.

This update is intended to provide market transparency during the ongoing exercise period for warrants of series TO12 between May 17 and May 30, 2024. As previously communicated Spago Nanomedical may receive approximately SEK 25.5 million before issuance costs upon full utilization of all TO12-warrants. The proceeds are primarily intended to be used to secure results from the phase I part of Tumorad-01 and support decisions regarding the focus and commencement of the phase IIa part of the study.

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

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.

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