PRESS RELEASE

Lund, Sweden, August 27, 2024

Spago Nanomedical's Phase I/IIa study Tumorad-01 continues following successful treatment completion of first patient group

Spago Nanomedical AB (publ) today announced that the independent Data Monitoring Committee (DMC) recommends to proceed the clinical phase I/IIa study Tumorad-01 with the candidate drug 177Lu-SN201, with inclusion of patients with different tumor types. The recommendation is based on an analysis of data from the first three treated patients in the study that the DMC considers shows a satisfactory safety profile. The study proceeds according to plan with recruitment of patients at the two hospitals activated so far.

Tumorad-01 is a phase I/IIa first-in-human study in patients with advanced cancer with the primary objective of evaluating the safety, tolerability, dosimetry and initial efficacy of the candidate drug 177Lu-SN201. The first patient group of three patients, two men with metastatic prostate cancer and one woman with metastatic breast cancer, has been successfully treated with at least one dose/cycle of 177Lu-SN201 (10 MBq/kg). The DMC has evaluated all available data for the patient population regarding safety, tolerability, biodistribution and dosimetry. No serious adverse events (SAEs) have been reported. Further, the DMC considers the safety to be satisfactory in this patient group and recommends the study to continue according to plan with inclusion of patients with different tumor types.

"The main objective of the phase I part of Tumorad-01 is to show that the treatment is safe and tolerated by patients. We are therefore very pleased with the DMC's recommendation, which is based on a thorough evaluation of the first three treated patients. We are now proceeding according to plan to recruit the next cohort, focusing on fulfilling a further objective of the protocol, recruiting patients with different tumor types," says CEO Mats Hansen.

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 based on safety and biodistribution. Patient recruitment is proceeding according to plan and additional patients have been identified and are expected to be included shortly. The next DMC evaluation is expected to occur after 3 additional patients complete a first treatment cycle.

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. In the Tumorad candidate drug 177Lu-SN201, the same type of carefully optimized polymeric nanomaterials 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.

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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