PRESS RELEASE

Lund, Sweden, March 4, 2025

Spago Nanomedical proceeds with increased dose in the phase I/IIa study Tumorad-01

Spago Nanomedical AB (publ) announced today that the independent Data Monitoring Committee (DMC) recommends a dose increase in the ongoing phase I/IIa study Tumorad-01 with the candidate drug 177Lu-SN201. The recommendation is based on analysis of data from two patient groups, consisting of six patients with five different cancer types. Both groups show similar acceptable safety profile.

"We are very pleased with the decision from the DMC and the study is now proceeding to the next dose level. The recruitment of patients with multiple tumor types is accelerating while we continuously strengthen the understanding of how 177Lu-SN201 works in different cancer types. This knowledge will be of great importance for the next step. Our goal to complete the phase I part of the study in 2025 remains unchanged," says CEO Mats Hansen.

The clinical phase I/IIa study Tumorad-01 is a first-in-human study with the 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. The second patient group in the study, consisting of three patients, two women with lung and throat cancer, respectively, and one man with rectal cancer, has now been treated with at least one dose-cycle of 177Lu-SN201. The DMC has conducted an analysis based on all available data for the two first patient groups and assesses that the safety profile in the patient groups is satisfactory and recommends to increase the dose in the study and continue the patient recruitment as planned.

A total of six patients with five different tumor types have been dosed in the study to date. In addition to the phase I primary objective of evaluating safety, an important secondary objective is to evaluate and develop imaging and dosimetry. Preliminary evaluation of the images that have been collected so far indicate biodistribution in line with preclinical results. Methods for optimal imaging and dosimetric calculations specifically adapted for 177Lu-SN201 are being continuously developed as the study progresses.

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, and that the DMC recommended that the study continue based on an evaluation of all data available at that time. The company has also received ethics approval to also include patients on a lower dose of 177Lu-SN201 in parallel. As such the study includes three dose levels so far and active recruitment to the higher and lower of these is now underway at two hospitals, Cancer Research SA in Adelaide and St Vincent's Hospital in Melbourne.

More information about the 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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