PRESS RELEASE

Lund, Sweden, October 14, 2025

Visible tumor uptake and recommended dose increase in Spago Nanomedicals's 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 clinical trial Tumorad-01 with the radiopharmaceutical drug candidate ^{177}Lu-SN201. In addition, significant visible tumor uptake of ^{177}Lu-SN201 has been observed on SPECT images, which can be considered a proof-of-concept for Tumorad in humans according to the DMC. This provides strong support for continued development, as well as basis for exploring opportunities in indications with potential for orphan drug designation.

Patient recruitment in the company's ongoing Phase I/IIa study Tumorad-01 has continued according to the current study protocol, and the third patient group is now fully recruited. A total of 12 patients with 10 different tumor types have been dosed, including three patients at the highest dose to date of 15 MBq/kg. An analysis of data from all patients treated to date confirms the previously demonstrated safety profile, i.e., that safety is acceptable and consistent. The independent Data Monitoring Committee (DMC) assesses that the maximum tolerable dose (MTD) has not yet been reached and recommends a further dose increase in the study.

"It is very gratifying that MTD has not yet been reached and that the DMC recommends a continued increase in dose, as this indicates that Tumorad has an acceptable safety profile so far. As with all cancer treatments, but perhaps even more so in radiotherapy, an acceptable safety profile is crucial. If we maintain the safety profile observed to date, this will be a significant advantage for Tumorad and a clear differentiating factor compared to other RNT drugs, both launched and in development, which often have more complex side effect profiles," says CEO Mats Hansen.

Visible tumor uptake of ^{177}Lu-SN201 has been observed with SPECT images in some participants. Significant levels of uptake have been observed in a patient with the rare cancer adenoid cystic carcinoma (ACC), who was treated with one cycle of ^{177}Lu-SN201 at the current highest dose level. The observed tumor uptake supports Tumorad's mechanism in humans and indicates potential for therapeutic exposure by means of delivery of the medically proven isotope ^{177}Lu. The independent monitoring committee considers the observation to be proof-of-concept for Tumorad, indicating that ^{177}Lu-SN201 may be a potential new treatment for cancer.

"The tumor uptake demonstrated with ^{177}Lu-SN201 in humans is a significant milestone for the Tumorad program and puts the company in a whole new position. In addition to confirming previous results with our platform technology, the uptake provides important support for the continued development of Tumorad and may open up development paths in indications with the potential for orphan drug status," continues CEO Mats Hansen.

ACC is an aggressive cancer that most often occurs in the salivary glands and usually appears between the ages of 40 and 60. The initial standard treatment is surgery or radiation, but there is currently no standard treatment for recurrent or metastatic disease.

The Phase I/IIa study Tumorad-01 is a first-in-human study designed to evaluate the safety, tolerability, dosimetry, and initial efficacy of ^{177}Lu-SN201 in cancer patients. The study is being conducted sequentially (stepwise), with fixed evaluations by an independent data monitoring committee (DMC), where the Phase I part of the study aims to identify the maximum tolerated dose (MTD) and/or a possible therapeutic dose for further testing in selected patient groups in the Phase IIa part of the study. The third patient group in the study, consisting of three patients, two men with liver cancer and one woman with ACC, has now been treated with at least one dose/cycle of ^{177}Lu-SN201.

The DMC has conducted an analysis based on all available data for the three patient groups and the DMC considers the safety profile to be manageable and consistent across all patients. The MTD has not yet been reached, and the DMC recommends that the Phase I part of the study continue with the recruitment of one additional patient at the dose of 20 MBq/kg.

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.

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 2025-10-14 11:33 CEST.

Visible tumor uptake and recommended dose increase in Spago Nanomedicals's Phase I/IIa study Tumorad-01