PRESS RELEASE

Lund, Sweden, June 3, 2025

Spago Nanomedical continues patient recruitment in the phase I/IIa study Tumorad-01 as planned after DMC recommendation

Spago Nanomedical AB (publ) announced today that the Data Monitoring Committee (DMC) recommends the ongoing phase I/IIa study Tumorad-01 with the candidate drug ^{177}Lu-SN201 to continue according to the current study protocol with the recruitment of additional two patients at the current highest dose. The recommendation is based on the analysis of data from all three patient cohorts totaling 10 dosed patients, which demonstrated a continued acceptable safety profile.

The DMC has recommended to continue the ongoing phase I/IIa study Tumorad-01 in accordance with the current study protocol. This follows the committee's earlier recommendation in March 2025 to proceed to a higher dose of ^{177}Lu-SN201. To date, 10 patients with 8 different tumor types have been dosed across three patient cohorts, including one patient on the highest current dose of 15 MBq/kg. An analysis of dosed patients shows that safety is acceptable and consistent across all patients. The observed side effects are mainly related to a transient impact on the platelets, which can be expected with radioactive treatment. The study continues with the recruitment of two additional patients at a dose of 15 MBq/kg alongside the ongoing dosing of patients at the lower dose of 5 MBq/kg.

"The recommendation to continue the study according to the current protocol is of great importance as it confirms that the safety profile of our candidate drug ^{177}Lu-SN201 remain acceptable even at the highest dose level tested to date. With three different dose levels evaluated in a larger number of patients with various tumor types, we will have a strong basis and good opportunities to develop the robust documentation needed for upcoming phases with a main focus on efficacy," says CEO Mats Hansen. "Patient recruitment is actively ongoing at the clinics in Australia, and we remain committed to completing the phase I part of the study within the current year."

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 ^{177}Lu-SN201 in cancer patients. The primary goal of the phase I part of the study is to assess safety and identify a possible therapeutic dose for further testing in selected patient groups in the phase IIa part of the study.

The third patient cohort in the study, consisting of one patient, an individual with liver cancer, has now been treated with one dose/cycle of ^{177}Lu-SN201. The DMC has conducted an analysis based on all available data across the three patient cohorts. No dose-limiting toxicity (DLT) has been reported, and the DMC assesses that the safety is acceptable and consistent across all patients.

The study currently includes three dose levels; 5, 10, and 15 MBq/kg, and active recruitment for the higher of these continues at two hospitals, Cancer Research SA in Adelaide and St Vincent's Hospital in Melbourne. In parallel, treatment of patients with repeated dosing of 5 MBq/kg continues. A total of approximately 12 patients are planned to be enrolled in the study. The company's target is to complete the phase I part of the study in 2025.

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

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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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