PRESS RELEASE

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Spago Nanomedical's phase I/IIa study Tumorad-01 meets a primary endpoint and provides further visible tumor uptake

Spago Nanomedical AB (publ) announced today that the independent Data Monitoring Committee (DMC) of the Tumorad-01 study declared that a primary endpoint, identifying the maximum tolerated dose, has been met and recommends that an additional two patients are enrolled at the dose level of 15 MBq/kg to provide a basis for defining a recommended phase II dose and completion of the phase I part of the study. Significant visible tumor uptake of ^{177}Lu-SN201 has been observed in an additional patient with head and neck cancer, strengthening proof-of-concept for the Tumorad program.

Patient recruitment in the ongoing phase I/IIa Tumorad-01 study has continued in accordance with the study protocol, and to date a total of 15 patients with advanced cancer have been dosed in the study. Based on data from the latest patient receiving 20 MBq/kg the independent Data Monitoring Committee (DMC) declared a primary study endpoint of maximum tolerated dose (MTD) has been met. The DMC further recommends that the study continues with recruitment of additional two patients at the second highest dose level of 15 MBq/kg to provide a basis for defining the recommended phase II dose (RP2D) and progress towards completion of the phase I part of the study. Preliminary data from all previously treated patients indicate an acceptable and consistent safety profile across dose levels up to 20 MBq/kg.

Visible tumor uptake of ^{177}Lu-SN201 was observed in SPECT/CT images of tumors from squamous cell carcinoma of the tongue (SCC), a form of head and neck cancer, in the patient treated with one cycle of ^{177}Lu-SN201 at the highest dose level of 20 MBq/kg. The observation is further supported by clearly visible uptake in tumor-affected lymph nodes. Earlier in the study, visible tumor uptake has been observed in treated patients, particularly prominent in one patient with adenoid cystic carcinoma (ACC), also a form of head and neck cancer. The tumor uptake supports the mechanism of action of Tumorad in humans and forms the basis for the DMC's previous assessment that the uptake can be considered proof-of-concept for Tumorad as a potential new treatment approach for advanced cancer.

The study now continues with fractionated treatment of two patients at the dose level 15 MBq /kg to provide additional basis for definition of a recommended phase II dose (RP2D), another primary objective of the study.

"Defining a recommended phase II dose represents an important endpoint of the phase I part of the study. If confirmed by the DMC following treatment of the next two patients, this will mark an important milestone for the Tumorad program. The observations of visible uptake in head and neck tumors provide further support for the program's potential. With this, we are in a stronger position as we move into the next stage," says CEO Mats Hansen.

The phase I/IIa Tumorad-01 study is a first-in-human study designed to evaluate the safety, tolerability, dosimetry, and initial efficacy of ^{177}Lu-SN201 in adult patients with progressive or treatment-resistant advanced, unresectable, or metastatic solid tumors. The study is conducted with predefined evaluations performed by DMC. Additional patients are to be enrolled in the patient cohort.

An important endpoint of the phase I part of the study is to identify the maximum tolerated dose (MTD) and/or a recommended therapeutic dose for phase II (RP2D). Current and upcoming data expected to provide a solid basis for continued development in phase II, where the focus will shift towards generating efficacy data in selected tumor indications.

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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