PRESS RELEASE

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Spago Nanomedical continues recruitment in the phase I/IIa Tumorad-01 study following positive DMC recommendation

Spago Nanomedical AB (publ) announced today that the independent Data Monitoring Committee (DMC) recommends that the ongoing clinical phase I/IIa study Tumorad-01 with the drug candidate ^{177}Lu-SN201 continues with parallel recruitment of two additional patients at the current dose level. The recommendation is based on an analysis of data from a total of 14 dosed patients across a broad spectrum of solid tumors, demonstrating a continued acceptable safety profile.

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 14 patients with advanced cancer have been dosed in the study. An analysis of data from all patients treated to date confirms the previously observed safety profile, i.e., the safety remains acceptable. The independent Data Monitoring Committee (DMC) has reviewed the available safety data and concluded that the maximum tolerated dose (MTD) has not yet been reached. The DMC therefore recommends that the study continues with parallel recruitment of an additional two patients at the current dose level.

Earlier in the study, visible tumor uptake of ^{177}Lu-SN201 was observed in SPECT/CT images in treated patients, which can be considered as proof-of-concept for Tumorad in humans. This observation supports the mechanism of action of Tumorad and indicates potential for therapeutic exposure using the clinically established isotope ^{177}Lu.

"The continued acceptable safety profile in patient groups with a broad range of solid tumors is encouraging, and the DMC's recommendation to expand the current dose cohort with parallel recruitment of an additional two patients indicates further margin to MTD, providing important support for the continued clinical development of Tumorad," says CEO Mats Hansen. "In parallel with determining the MTD and establishing dosing for phase II, our focus is now on regulatory interactions aimed at more clearly defining the path forward for the program, including exploring the potential for orphan drug designation."

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 sequentially, with predefined evaluations performed by DMC. The objective of the phase I part of the study is to identify the MTD or a recommended therapeutic dose for further evaluation in selected patient groups in the phase IIa part of the study.

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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