PRESS RELEASE

Lund, Sweden, October 1, 2024

Spago Nanomedical in new phase with full focus on the Tumorad program

The Board of Directors of Spago Nanomedical AB (publ) has decided that the company's resources will be focused on the development of Tumorad with the company's primary priority being the execution of the ongoing clinical study Tumorad-01 with the candidate drug 177Lu-SN201. To ensure that crucial clinical milestones can be reached and to position the company well for the future, organizational changes will be made.

The Board of Directors of Spago Nanomedical has established a strategy focused on areas of opportunity for clinical success and to create shareholder value in the short to medium term. The company's resources will primarily be focused on the ongoing phase I/IIa study Tumorad-01. The aim is to generate results from the phase I part of the study using existing cash, which will support decisions on the continued clinical development and start of the phase IIa part of the study.

The focus on the Tumorad program results in that internal preclinical discovery activities will cease. This is expected to lead to significantly reduced costs and financial space to ensure results that can support decisions on the continued clinical development and prepare for the next phase of the Tumorad program.

"Spago Nanomedical is in a new phase with full focus on the development of our candidate drug against cancer, 177Lu-SN201. The plan established is crucial to advance and accelerate the development of our leading Tumorad program. Following the recent recommendation of the independent Data Monitoring Committee (DMC) to continue as per protocol with the inclusion of patients with different tumor types, we are now increasing the recruitment rate at two clinical sites and expect to be able to evaluate the next patient cohort after the end of the year." says CEO Mats Hansen. "It is of course regrettable that the measures decided on include staff reductions, but it is a natural consequence of the company being in a new phase and that we choose to focus our resources on areas where we see the greatest potential in the near future. With the significant market potential and the growing interest in the radionuclide therapy area among both investors and pharmaceutical companies, I'm convinced that this priority is right."

The Phase I/IIa clinical study Tumorad-01 is a first-in-human study with the primary objective 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. In August 2024, the company announced that the first patient group of three patients had been successfully treated with at least one dose of 177Lu-SN201. Further, the DMC recommended the study to continue according to plan with the inclusion of patients with different tumor types. The recommendation was based on an analysis of all available data for the patient group regarding safety, tolerability, biodistribution and dosimetry. No serious adverse events (SAEs) had been reported and the DMC considered the safety to be satisfactory in this patient group. Patient recruitment is proceeding according to plan at two clinical sites and the next DMC evaluation is expected to occur after the next cohort of three patients have completed the first treatment cycle.

The SpagoPix development program, with the product candidate pegfosimer manganese, aims to improve the precision of MRI scanning of suspected endometriosis and cancer by launching a selective contrast agent for more precise visualization of tumors and other lesions. Initial clinical results show that pegfosimer manganese provides clinically relevant contrast in breast cancer tumors, in the liver and in the pancreas, while maintaining good safety. Selective contrast enhancement has also been observed in endometriosis lesions in a phase IIa clinical trial. Any further clinical development within the SpagoPix program will take place in collaboration with a partner, through out-licensing, commercial collaborations or other types of grants. Active business development work is underway to find potential partners or other solutions for the continued development of the program.

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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