PRESS RELEASE

Lund, Sweden, October 19, 2023

Spago Nanomedical receives approval to initiate the clinical phase I/IIa study with Tumorad® in Australia

Spago Nanomedical AB (publ) announces today that the company's application to start the clinical phase I/IIa study, Tumorad-01, with the candidate drug 177Lu-SN201 in cancer patients has been approved. The first patient is expected to be included shortly.

"We are very excited and strongly motivated to now start the first clinical study with Tumorad. The study is designed in such a way that we can expect initial data showing the biodistribution and accumulation of 177Lu-SN201 in tumors of cancer patients early in the phase I part of the study. With a favorable distribution of radiation to tumors versus the rest of the body, 177Lu-SN201 has good potential for becoming an effective drug against cancer," says CEO Mats Hansen.

Full approval to start the study has been obtained from the ethics review committee at St. Vincent's Hospital in Melbourne, and it has been registered with the Australian Therapeutic Goods Administration (TGA). Site initiation is being conducted immediately and patient recruitment is expected to follow immediately thereafter.

In addition to competent clinics, Australia offers several regulatory and financial advantages that allow the company to bring Tumorad to cancer patients quickly and cost-effectively. The possibility for substantial reimbursement of R&D costs is a great advantage, as is the familiarity of authorities and hospitals with radiopharmaceuticals and access to local manufacturing and distribution of the radioisotope lutetium-177.

The approved clinical study is a phase I/IIa, dose escalation and dose expansion, first-in-human study in patients with advanced cancer. The primary aim of the entire study is to evaluate safety, tolerability and initial efficacy of 177Lu-SN201. The phase I part of the study will include up to 30 cancer patients with the aim to identify a possible therapeutic dose based on safety and biodistribution, to be further tested in selected groups of patients during the phase IIa part. A favorable distribution of radiation to tumors versus the rest of the body provides good conditions for 177Lu-SN201 to become an effective pharmaceutical against cancer. The study will initially be conducted at number of sites in Australia and as the study progress, sites in other countries may also be included. The aim is for the first patient to be included in the fourth quarter of 2023.

Study details and updates will be published at www.clinicaltrials.gov.

Clinical evidence of selective tumor accumulation of Spago Nanomedical´s functional nanoparticles has previously been generated with the MRI contrast agent SN132D in patients with breast cancer. The radioisotope lutetium-177 (177Lu) is clinical effective against cancer and is used already today in market approved drugs. Combined with Spago Nanomedical´s carefully designed polymeric nanomaterial, the candidate drug 177Lu-SN201 provides for a promising new radionuclide therapy for tumor selective treatment of cancer with potential use

in several different tumor types. The Tumorad-01 study is designed to enable early results showing biodistribution and accumulation of 177Lu-SN201 in tumors in cancer patients. With a favorable distribution of radiation to tumors compared to other organs, 177Lu-SN201 has good potential to become an effective drug against cancer.

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 nanomedicines company in clinical development phase. The company´s development projects are based on a platform of polymeric materials with unique properties for more precise diagnosis and treatment of life-threatening and 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 2023-10-19 07:02 CEST.

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