

## PRESS RELEASE

Lund, Sweden, May 23, 2023

# Spago Nanomedical has submitted application to start Tumorad® clinical phase I /IIa study

Spago Nanomedical AB (publ) today announced that the final step in the preparations for the clinical phase I/IIa trial in cancer patients, Tumorad-01, with its leading candidate drug <sup>177</sup>Lu-SN201 has begun in Australia. The application to start the study has been sent to the ethics committee and patient enrollment is expected to start in the summer 2023.

The application process includes submission to an Australian Human Research Ethics Committee (HREC), followed by a Clinical Trial Notification (CTN) to the Australian Therapeutic Goods Administration (TGA). Patient recruitment is expected to start immediately following approval.

*"This marks the transition into clinical development of our radionuclide therapy program Tumorad and is a very important milestone for Spago Nanomedical. Australia offers an excellent framework for our study by provision of several competent clinical sites, an expedited regulatory pathway, and beneficial financial support of R&D costs. This allows us to bring Tumorad to cancer patients in a rapid and cost-effective way, and we expect to include the first patient in the summer,"* said CEO Mats Hansen.

Spago Nanomedical plans to commence clinical development of <sup>177</sup>Lu-SN201 with a phase I /IIa, dose escalation and dose expansion, first-in-human study in patients with advanced cancer. The primary aim of the study is to evaluate the safety, tolerability and early efficacy of <sup>177</sup>Lu-SN201. The Phase I part of the study will include up to 30 patients. Study details and updates will be published at [www.clinicaltrials.gov](http://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 (<sup>177</sup>Lu) is clinically effective against cancer. Combined with Spago Nanomedical's carefully designed polymeric nanomaterial, the candidate drug <sup>177</sup>Lu-SN201 provides for a promising new radionuclide therapy for physiological targeting and tumor selective treatment of cancer with potential use in several different tumor types.

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For further information, please contact Mats Hansen, CEO Spago Nanomedical AB, +46 46 811 88, [mats.hansen@spagonanomedical.se](mailto:mats.hansen@spagonanomedical.se)

*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](http://www.spagonanomedical.se).*

*FNCA Sweden AB is the Certified Adviser of the company.*

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