

PRESS RELEASE

Lund, Sweden, December 6, 2022

Spago Nanomedical initiates clinical trial with SpagoPix in endometriosis and concludes SPAGOPIX-01

Spago Nanomedical AB (publ) today announced that the company has received regulatory approval to initiate a Phase IIa clinical study with its MRI contrast agent SN132D in endometriosis – a chronic, debilitating condition that affects up to 10 percent of women of reproductive age. Patient recruitment has started, and the first patient is expected to be dosed shortly. The ongoing SPAGOPIX-01 study in breast cancer has now been concluded and a final report is in preparation.

“We are very pleased that SPAGOPIX-01 meets the primary objectives set out for the study and that the results with SpagoPix in breast cancer provide a clinical validation of our nanomedical platform. Based on ongoing discussions with potential partners and experts in the field, we have decided to focus our resources within the SpagoPix program on endometriosis, a severely undertreated disease affecting up to 10 percent of women of reproductive age,” said Mats Hansen, CEO at Spago Nanomedical.

“Endometriosis represents a very large indication of major unmet medical need for better imaging diagnostics which current contrast agents and other diagnostics are not able to fulfil,” he continued.

The Phase IIa clinical trial in endometriosis is an open label, proof-of-concept study concerning efficacy of the novel intravenous contrast agent SN132D in patients with suspected endometriosis. The study will include up to 18 patients and led by Associate Professor Dr. Ligita Jokubkiene, Senior Consultant at the Department of Obstetrics and Gynecology at Skåne University Hospital in Malmö, Sweden.

The study will evaluate the safety and MRI enhancing properties of SN132D in participants with suspected endometriosis. Comparisons will be made to transvaginal ultrasound and conventional MRI in order to consider the diagnostic potential of SN132D in endometriosis.

“Endometriosis is a chronic condition that has a tremendous effect on the quality of life for so many women and girls. Pain and infertility are the clinical hallmarks of the disease, affecting not only those affected with endometriosis, but also their partners, families, and the wider society. The need for better treatments options and initial diagnosis enabling early detection of the disease is vast. I am excited to lead this highly anticipated trial and to provide hope to women around the world suffering from endometriosis,” said Associate Professor Dr. Ligita Jokubkiene

The SPAGOPIX-01 study in breast cancer was conducted at two hospitals in Sweden with the primary objective of studying safety at different doses of SN132D. A total of 14 patients with confirmed breast cancer were enrolled and dosed. The initial results from the study will be presented at the 2022 San Antonio Breast Cancer Symposium and the final report of the study is in preparation.

SN132D in endometriosis

Endometriosis is a chronic disease of the female reproductive system in which cells similar to those in the endometrium, the layer of tissue that normally covers the inside of the uterus, grows outside the uterus, causing menstrual pain, pain at defecation and sexual intercourse, chronic pelvic pain and infertility. Like cancer, endometriosis is an angiogenesis-dependent disease that could be targeted by means of optimized functional nanoparticles.

It is estimated that more than 176 million women of reproductive age are affected worldwide and endometriosis accounts for societal healthcare costs of a similar order as diseases such as type 2 diabetes or rheumatoid arthritis. Access to early diagnosis and effective treatment of endometriosis is important. Currently, the average time to diagnosis is 7 years and the clinical need for improved diagnostic technologies is high.

Endometriosis represents a major market for any diagnostic agent that can improve, non-invasively, the rate of correct diagnosis. The estimated total addressable market for SN132D in endometriosis is €500M annually, which is significantly larger than that of breast cancer where the competition with current standard MRI and other modalities is higher.

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 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.

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