PRESS RELEASE

Lund, Sweden, December 15, 2023

Spago Nanomedical reports positive top line data from clinical phase IIa study SPAGOPIX-02 in patients with endometriosis

Spago Nanomedical AB (publ) announces today that the analysis of data from the phase IIa clinical study SPAGOPIX-02 with the contrast agent pegfosimer manganese (formerly SN132D) confirms that the primary endpoint of measuring the MRI enhancing effect in endometriotic lesions was met, with an overall acceptable safety profile.

The analysis of MR-images from the SPAGOPIX-02 clinical study shows that the primary endpoint of measuring the MRI enhancing effect in endometriotic lesions that was identified by the treating gynaecologist was met. Contrast enhancement with pegfosimer manganese was observed in the majority of lesions confirmed by unenhanced ultrasound. In addition, the overall safety was considered acceptable, confirming the previously announced preliminary conclusion by the study Data Monitoring Committee (DMC).

"We have achieved the purpose of the study and show the potential of pegfosimer manganese in medical imaging of endometriosis lesions. The results and conclusions from this first clinical trial are encouraging. This provides confidence and generates hypotheses to be evaluated in the next steps", said Dr. Ligita Jokubkiene, MD and Senior Consultant at Skåne University Hospital and Principal Investigator of the trial.

Exploratory analysis is suggestive of enhancement in active inflammatory lesions but not of indolent fibrotic lesions, suggesting the clinical relevance of pegfosimer manganese-enhanced MRI, which may be of great importance for disease staging and treatment planning.

"The promising results and conclusions from this first clinical trial with pegfosimer manganese in endometriosis strengthen our belief in pegfosimer manganese as a novel contrast agent with the potential to significantly improve the precision of MRI in this group of underserved patients", said Mats Hansen, CEO of Spago Nanomedical.

SPAGOPIX-02 is an open-label, proof-of-concept study with the primary objective to evaluate the MRI enhancing properties of the novel lesion selective MRI contrast agent pegfosimer manganese in patients with suspected endometriosis. Secondary objectives included evaluations of the diagnostic value of pegfosimer manganese for detection of endometriosis lesions, specifically deep pelvic endometriosis lesions, and safety.

The full analysis of results continues along with compilation of the clinical study report. Final results will be published later in one or several appropriate scientific journals and at scientific conferences.

The contrast agent, previously known only as SN132D, has been granted the official generic name (International Nonproprietary Name (INN)) pegfosimer manganese by the World Health Organisation (WHO). From now on, the generic name will be used in all external communications.

Pegfosimer manganese has previously been evaluated in the phase I clinical study SPAGOPIX-01 in patients with confirmed breast cancer. Results from the study show that the contrast agent is well tolerated and provides clear contrast in MRI images of solid tumors in the breast, as well as in the pancreas and liver.

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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.

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 2023-12-15 11:45 CET.

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