

PRESS RELEASE



SPL Medical announces the first time mentioning of its novel contrast agent Ferrotran® (Ferumoxtran) in the German S3-guidelines for Prostate Cancer

- Novel imaging agent mentioned in German S3-Guidelines Prostate Cancer

Nijmegen, Netherlands, 27.05.2021 – SPL Medical announced today that the new issue of the German S3-guidelines for prostate cancer, released this month by the Guideline Program Oncology of the German Cancer Society, Deutsche Krebshilfe and AWMF, for the first time is mentioning Ferrotran® (Ferumoxtran) on page 25 of the Guideline Report document.

The full guideline document can be downloaded at:

<https://www.leitlinienprogramm-onkologie.de/leitlinien/prostatakarzinom>

Ferrotran® (Ferumoxtran) is a novel contrast agent for use in MRI (magnetic resonance imaging) developed for the detection of lymph node metastases of prostate cancer. It is the first contrast agent for the use in MRI that is able to identify lymph node metastases as small as 2 mm. Being able to detect small metastases in prostate cancer early enough could enable a better chance of successful treatment.

SPL Medical is the manufacturer of Ferrotran® and responsible for the worldwide commercialization. The company has launched a multicenter phase III trial for Ferrotran® in major radiology / urology centers in Germany, Switzerland and the Netherlands, expecting to enroll a total of 180 patients with prostatic cancer.

Since 2014, more than 700 patients successfully underwent nano-MRI with Ferrotran® in various clinical trials, a named-patient use program at Radboud university medical center (Radboudumc) in Nijmegen, The Netherlands, and a compassionate use program in Switzerland at the University Hospital Zurich.

“In the last years we have built up a vast expertise in Ferrotran-enhanced nano-MRI® and are training radiologists from participating clinical centers to bring them up to speed with the latest use of the product and interpretation of the imaging,” said Dr. Jürgen Feuerstein, Chief Executive Officer of SPL Medical.

“nano-MRI by Ferrotran® represents a major opportunity to improve the diagnosis of lymph node metastases in prostate cancer patients, subsequently having potentially better treatment possibilities and fewer side effects,” stated Dr. Jürgen Feuerstein. “The compassionate use program at the Zurich University Hospital and the Radboudumc, Nijmegen named-patient program provide vital access for prostate cancer patients to this game-changing product. Meanwhile, at SPL Medical, we will continue advancing our clinical development plan to enable potential registration of Ferrotran® and seeking for special access programs in further countries for bridging patient access to this technology beneficial for prostate cancer patient treatment.”

About Ferrotran®:

Ferrotran® belongs to the group of USPIO's (Ultrasmall Superparamagnetic Particles of Iron Oxide) and is the only contrast agent that can detect lymph node metastases as small as 2 mm. Standard MRI, CT or PET scans are normally not able to detect such small metastatic lymph nodes. Since the vast majority of prostate cancer patients are dying due to metastases, a precise diagnosis on this field is of utmost importance. The detection of small metastases, combined with a very clear contrast of the nano-MRI with the administration of Ferrotran®, giving also excellent visualization of vessels, enables an earlier and more precise treatment.

About SPL Medical:

SPL Medical is a spin-off of the Radboud university medical center and is funded additionally by Oost NL, a Dutch regional venture capital company, and b.e.imaging GmbH, a German company specialized in the development and commercialization of contrast agents.

For more information about Ferrotran®, the clinical trials or SPL Medical:

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For further information please visit: www.ferrotran.com