

PRESS RELEASE

Nijmegen, March 7, 2019

Bfarm gives green light to SPL Medical for its phase 3 pivotal clinical trial with Ferrotran[®], a novel MRI contrast agent for the (early) detection of Lymph node metastases!

Bfarm, the German regulatory body for pharmaceutical products, has set the way free for the start of the important multicenter trial of Ferrotran[®] (Ferumoxtran), a novel contrast agent for use in MRI (magnetic resonance imaging) developed for the (early) detection of lymph node metastases of prostate cancer.

The clinical trial will be performed in 10 top radiology centers in Germany, Switzerland and the Netherlands, and a total of 180 patients with prostatic cancer will be selected for the trial.

Ferrotran[®] was recently approved in Switzerland for compassionate use (Sonderbewilligung) in the diagnosis of detection of lymph node metastases of prostate cancer patients.

According to Professor Bernd Hamm, the principal investigator of the trial and Head of the Dept. of Radiology of the famous Charité hospital in Berlin: "The outcome of this trial will give new insights into the value of Ferrotran in the (early) detection of lymph node metastasis from prostate cancer. Better detection or exclusion of lymphatic cancer spread markedly affects treatment decisions and will improve outcome for patients."

The development of Ferrotran[®] was accelerated when Prof. Jelle Barentsz of the Radboud University Medical Center in Nijmegen, the Netherlands further explored the unique features of Ferrotran[®] for the early detection of lymph node metastases when he used it as contrast agent for his prostate cancer patients. So far, he diagnosed more than 1200 patients in earlier clinical trials and name-patient use application. "We have built a vast experience with Ferrotran[®] and have started to train radiologists from participating clinical centers to bring them up to speed with the latest use of the product and interpretation of the imaging results".

The first patient will be enrolled as soon as the ethics committee has approved the trial. Dr. Patrik Zamecnik, medical advisor for the trial is optimistic about a rapid enrollment of the 180 patients: "The medical community is eagerly waiting for the outcome of this trial which will be a major breakthrough in the diagnosis of this type of cancer."

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 co-investor **b.e.imaging**, a leading German provider of diagnostic imaging.

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 metastasis as small as 2 mm. Standard MRI or CT are normally not able to detect nodes smaller than 7-8 mm. Since most prostate cancer patients are dying due to metastases, a precise diagnosis is of utmost importance. The detection of small metastases, combined with a very clear and contrast rich MRI image of Ferrotran®, enables an earlier and more precise treatment. Therefore, it is to be expected that a patient has a much higher chance of full recovery and a higher quality of life.

For more information about the clinical trial centers or SPL Medical:

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