



PRESS RELEASE

SPL Medical receives approval for Clinical Trial with contrast agent Ferrotran® in 10 top radiology centers.

SPL Medical BV has received approval of the German regulatory body for pharmaceutical products BfArM, to the start of a multicenter clinical trial of Ferrotran®. This is a novel contrast agent (based on Ferumoxtran-10) for use in MRI (magnetic resonance imaging), developed for the (early) detection of lymph node metastases of prostate cancer. Ferrotran® is the only contrast agent that can detect lymph node metastases as small as 2 mm. Standard MRI or CT are normally not able to detect nodes smaller than 7-8 mm.

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. The first patient will be enrolled as soon as the ethics committee has approved 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 this 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, Chairman of the Prostate MRI Expert Center 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 1.200 patients in earlier clinical trials and name-patient use applications.

“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,” stated Prof. Dr. Jelle Barentsz.

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 GmbH, 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 lymph nodes smaller than 7-8 mm. Since most prostate cancer patients are dying due to metastases, a precise diagnosis incl. lymph node staging 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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For further information:

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