

PRESS RELEASE

SPL Medical announces fast achievement of next major clinical development milestone for its breakthrough platform product Ferrotran®: 100 patients included in Phase III trial

Nijmegen, The Netherlands, 04.01.2023 – SPL medical has its proprietary iron-based nanoparticle Ferrotran® (Ferumoxtran) product and platform in clinical Phase III. The pivotal trial named PROSTAPROGRESS has now reached the next major milestone by inclusion of 100 patients into this trial.

Major academic centers in The Netherlands, Belgium, Germany and Switzerland are contributing constantly.

With the PROSTAPROGRESS trial, SPL will verify the superior efficacy and state-of-the-art safety of Ferrotran®, the lymphotropic nanoparticle of SPL medical, for the detection of lymph node metastases for prostate cancer patients with Magnetic Resonance Imaging (MRI).

The Ferrotran® particle has been developed as a platform technology for various applications for the broad base of installed MRI scanners worldwide.

With this achievement, SPL medical can envision application for market approval in Europe by the end of 2023 already.

- *"Having now included 100 patients so quickly after having reached the 50% inclusion milestone is a major milestone in the clinical phase III development and brings Ferrotran® even closer to market authorization application", says Dr. Jürgen Feuerstein, CEO for SPL medical.*
- *"We are very pleased to have achieved this next milestone so quickly. The dedication of the clinical sites in participating prestigious academic centers underlines the attractiveness and clinical need for an advanced lymph node imaging for the sake of improved patient diagnosis, treatment, and hence clinical outcome".*

About Ferrotran®:

Ferrotran® belongs to the group of USPIO's (Ultrasmall Superparamagnetic Particles of Iron Oxide). Ferrotran® can be applied in MRI as a safe blood pool agent for angiography and for functional diagnostics in detection of even the smallest lymph node metastases in prostate cancer patients and is currently under investigation for use in various other cancers.

Ferrotran® is safe, as it is based on iron and therefore metabolized naturally in the body.

Ferrotran® is in advanced phase III in various prestigious European University Hospitals.

Ferrotran® has been applied successfully in over 700 patients in the Netherlands and Switzerland in special approval permissions.

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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