PRESS RELEASE

Ferumoxtran, the iron-based investigational MRI contrast agent of SPL Medical B.V., meets primary endpoints in pivotal Phase III study.

Nijmegen, The Netherlands, 25.02.2025 – SPL Medical B.V. announced today the headline results of the pivotal phase III study PROSTAPROGRESS (EudraCT 2018-004310-18), aiming to assess the diagnostic accuracy of Ferumoxtran enhanced Magnetic Resonance Imaging (MRI) for lymph node detection in prostate cancer patients.

Ferumoxtran is an Ultrasmall Superparamagnetic Particle of Iron Oxide (USPIO). It does not contain Gadolinium but is based on iron, a physiologically required metal. The dosage applied, 2.6 mg Fe/kg body weight, is significantly lower than the usual dosage for the widely used i.v. iron substitution products.

The multicentric prospective PROSTAPROGRESS study confirmed the sensitivity and specificity primary endpoints.

Angiography data from the trial could show mostly excellent or good angiography readability as judged by the central readers of the trial.

The safety data from the ongoing safety monitoring revealed consistency with other major MRI contrast agents on Gd-basis.

“Meeting the primary endpoints in the PROSTAPROGRESS trial is a major milestone in the process to making Ferumoxtran available on a broad basis to medical professionals. Now we are eager to bringing Ferumoxtran to the market after regulatory approval has been achieved”, said Dr. Jürgen Feuerstein, CEO SPL Medical B.V.

“This opens great opportunities for further clinical development of Ferumoxtran, a contrast which has the potential to significantly improve lymph node metastasis detection using MRI” , said Dr. Patrik Zamecnik, Medical Advisor to SPL Medical B.V.

About the phase III study PROSTAPROGRESS
PROSTAPROGRESS (EudraCT 2018-004310-18) included prostate cancer patients with a medium to high risk of lymph node metastases and without prior treatment in renowned university centers in Germany, Netherlands, Belgium and Switzerland. The study was concluded in January 2025.

About Ferumoxtran
Ferumoxtran belongs to the group of USPIO’s (Ultrasmall Superparamagnetic Particles of Iron Oxide). Ferumoxtran can be applied in MRI as a safe bloodpool agent for angiography and for functional diagnostics in detection of even very small lymph node metastases. Ferumoxtran is available already now in a named-patient-use program in Nijmegen, Netherlands.

About MRI
Contrast enhanced MRI plays a key role in medical diagnostics with estimated annual procedures above 60 million. MRI is a radiation free method providing essential information for medical practice to support physicians in patient treatment by providing information in relation to detect, characterize and monitor diseases.

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 the major shareholder b.e.imaging GmbH, a German company specialized in the development and commercialization of contrast agents.

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