PRESS RELEASE

SPL medical has applied for Market Authorization of its innovative MRI contrast in major EU countries.

Nijmegen, The Netherlands, 13.03.2026 – SPL Medical B.V. announced today that the Market authorization Application (MAA) for its innovative MRI contrast based on Ferumoxtran has been validated by the competent authorities. Ferumoxtran, with the intended name Ferrotran®, is an iron oxide nanoparticle (USPIO) with specific lymphotropic and bloodpool properties as investigated successfully in 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.
Patients with known prostate cancer with intermediate to high risk of lymph node metastases without prior treatment were enrolled in the trial.
The multicentric prospective PROSTAPROGRESS study has not only confirmed the primary endpoints but also has been successful in the achievement of further secondary endpoints.
Additionally, a post-hoc analysis revealed elevated sensitivity and specificity data for metastatic lymph node lesions at levels beyond current technologies (Pienta et al. J Urol. 2021 July;206(1): 52–61).

The market authorization application via a decentralized procedure (DCP) has be filed on December 23, 2025 in a joint project with the licensees of SPL medical, b.e.imaging Gmbh and Sanochemia GmbH for their respective territories.

“This MAA is marking the next important step for the process to make Ferumoxtran available to the radiologists in the respective countries. Ferumoxtran, reflecting metastatic lesions in Prostate Cancer patients as small as 2 mm, can be regarded as major technology breakthrough. Bringing Ferumoxtran to the market after regulatory approval has been achieved will be our final big milestone, as the technology promises to be beneficial for prostate cancer patients”, said Dr. Jürgen Feuerstein, CEO SPL Medical B.V.

“The introduction of Ferumoxtran-enhanced MRI represents a major achievement in imaging of lymph nodes in prostate cancer patients. It provides high-resolution imaging without the need for ionizing radiation, detecting even small intra-nodal metastatic deposits. Also, it is using existing MRI infrastructure – already now installed scanners without the need of hardware modifications. We expect that this technique could improve diagnostic confidence and patient management in prostate cancer patients”, said Dr. Patrik Zamecnik, Medical Advisor to SPL Medical B.V.

About Ferumoxtran
Ferumoxtran belongs to the group of USPIO’s (Ultrasmall Superparamagnetic Particles of Iron Oxide). 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.
Ferumoxtran has the potential to 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 used already now in a named-patient-use program in Nijmegen, Netherlands.
Through the cell-specific uptake of Ferumoxtran in the macrophages an accumulation of Ferumoxtran in the healthy part of the lymph node(s) is provided. As a consequence, an artifact in MRI is causing loss of signal of the healthy part of the lymph node(s). Contrary to that, metastatic deposits do not contain macrophages with Ferumoxtran, retaining their high-signal in MRI. Since the used MR-sequences have high spatial resolution (typically around 0.8 mm isotropic), even very small metastatic intra-nodal deposits down to 2 mm in diameter can be detected. Additionally, this kind of imaging is independent from the (degree of) expression of specific antigens on the surface of the tumor cells or their metabolic activity by accumulation of Ferumoxtran in the healthy part of the lymph node resulting in the signal loss (“negative contrast”). This principle is unique in lymph node imaging providing a principal information regarding the presence (or absence) of abnormal deposits in the lymph nodes with high spatial resolution.

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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For further information please visit: www.splmed.com