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Marketing Authorization for TOCscan® (^{68}Ga-Edotreotide) in Germany, Austria and France

ITM receives marketing authorization for a ready-to-use radiopharmaceutical in 3 European countries

TOCscan® will be the companion diagnostic in ITM´s theranostic approach for the treatment of Neuroendocrine Tumors

ITM Isotopen Technologien München AG, a specialized radiopharmaceutical company, announced today that its subsidiary, ITG Isotope Technologies Garching GmbH, received marketing authorization for the ready-to-use radiopharmaceutical ^{68}Ga-Edotreotide (Gallium-68-DOTATOC) in Germany, Austria and France. The diagnostic agent ^{68}Ga-Edotreotide will be distributed under the brand name TOCscan® (Sogacin® in Austria / France).

TOCscan® will be used to diagnose neuroendocrine tumors (NETs) and localize metastases through the Targeted Radionuclide Therapy approach, which includes diagnosis as well as therapy. The diagnostic tool TOCscan® binds specifically to SST receptors on the tumor's surface by using the targeting molecule Edotreotide. Diagnostic images are produced via positron emission tomography (PET) by mapping the location of the medical radioisotope ^{68}Ga. This allows for the precise characterization of NETs pre-therapy as well as the evaluation of treatment response post-therapy. The quality of diagnostic imaging has improved significantly as a result of the use of PET with ^{68}Ga-DOTA-conjugated peptides such as TOCscan®. Another advantage of PET, in addition to the high sensitivity, is the ability to provide quick procedures with reduced imaging time. This has the effect of exposing the patient to less radioactivity.[1]

Following the determination of SSTR expression using PET, Targeted Radionuclide Therapy with n.c.a. ^{177}Lu-labeled Edotreotide for personalized treatment can be applied. ITM´s therapeutic radiopharmaceutical for NET, known as Solucin® (^{177}Lu-Edotreotide / ^{177}Lu-DOTATOC), is currently in the phase III clinical trial COMPETE. Solucin® and TOCscan® as the companion diagnostic act as an excellent theranostic pair for Precision Oncology. This personalized medicine approach is regarded as a substantial improvement to patient outcome and safety.

Steffen Schuster, Chief Executive Officer of the ITM Group, commented: *"We are delighted to have received marketing authorization for TOCscan®. As there are only few suitable and well tolerated treatment options for NET, we are looking forward to bringing TOCscan® as the diagnostic element of our Targeted Radionuclide Therapy approach to market. Theranostics offer a unique promise for the personalized treatment of cancer since we have the chance to »see what to treat«!"*

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About Targeted Radionuclide Therapy
Targeted Radionuclide Therapy uses very small amounts of radioactive compounds, called radiopharmaceuticals, to diagnose and treat various diseases, such as cancer. A targeted radiopharmaceutical contains a targeting molecule (e.g. peptide or antibody) and a medical radioactive isotope. The technique works by injecting the radio-conjugate into the patient's body where it accumulates in the affected organs or lesions. The targeting molecule binds, for example, to tumor-specific receptors or antigens, according to a lock and key principle, and is absorbed by the tumor cells. In most cases, the targeting molecule can be used for both diagnosis and therapy – only the radioisotope has to be changed. This opens up the way for the application of Theranostics.

For diagnostic applications, radioisotopes with short half-lives are utilized. With highly sensitive molecular imaging technologies like PET (Positron Emission Tomography) or SPECT (Single Photon Emission Tomography), images of organs and lesions can be created, and diseases can be diagnosed in their early stages. Medical radioisotopes with longer half-lives are then applied for treatment. The tumor tissue is destroyed by the radiopharmaceutical, which emits cytotoxic doses of ionizing radiation. A highly precise localization of the radioactivity ensures that healthy tissue in the surroundings of the targeted tumor is only minimally affected.

About TOCscan® / ^{68}Ga-Edotreotide
TOCscan® contains the targeting molecule Edotreotide (DOTATOC), an octreotide-derived somatostatin analogue, labeled with the medical radioisotope Gallium-68 (^{68}Ga). Edotreotide contains DOTA which functions as a chelator for radioisotopes and TOC, a synthetic somatostatin receptor agonist. It binds with high affinity to somatostatin receptors and retains both its receptor binding properties and its physiological function when labeled with ^{68}Ga. Somatostatin receptors are predominantly overexpressed by neuroendocrine tumors. TOCscan®, upon binding to SST receptors in vivo, is internalized and retained by tumor cells.

TOCscan® is used for PET or PET/CT molecular imaging of neuroendocrine tumors (NETs). As well as for diagnosis and staging of NETs, TOCscan® imaging is used for therapy planning and dosimetry in preparation for ^{177}Lu-Edotreotide (Solucin®) or ^{90}Y (Yttrium-90) DOTA therapy. TOCscan® will be provided as a ready-to-use injection. Significant benefits of TOCscan® include an outstanding PET imaging quality, improved patient management, low radiation exposure for the patients and the availability of quick procedures with short imaging time.[1]

About Solucin®
Solucin® (n.c.a. ^{177}Lu-Edotreotide / n.c.a. ^{177}Lu-DOTATOC) is known as an innovative therapeutic radiopharmaceutical with favorable safety profile and promising efficacy. Solucin® consists of two molecular components – Edotreotide and EndolucinBeta® (no-carrier-added Lutetium-177) a synthetic, low-energy beta-emitting isotope of Lutetium. Edotreotide binds with high affinity somatostatin receptors. Solucin®, upon binding to SST receptors in vivo, is internalized and retained by tumor cells. Upon decay, the isotope emits cytotoxic medium-energy beta particles of ≤1.7 mm path length in soft tissue.

The radioactive isotope EndolucinBeta® respectively n.c.a. ^{177}Lu chloride is used for treatment in Targeted Radionuclide Therapy. It is a radiopharmaceutical precursor, used for radiolabeling of disease-specific carrier molecules. EndolucinBeta® has a half-life of 6.647 days and provides the highest specific activity of more than 3,000 GBq/mg at Activity Reference Time (ART), whereas the day of ART can be flexibly selected by the customer. EndolucinBeta® exhibits an extraordinary level of radionuclidic purity. It does not contain metastable ^{177m}Lu, thus, there is no need of logistics and storage of contaminated radioactive waste. EndolucinBeta® is GMP certified and received marketing authorization in the EU in 2016.

About ITM

ITM Isotopen Technologien München AG is a privately held group of companies dedicated to the development, production and global supply of innovative diagnostic and therapeutic radionuclides and radiopharmaceuticals. Since its foundation in 2004, ITM and its subsidiaries have established the GMP manufacturing and a robust global supply network of a novel, first-in-class medical radionuclides and -generator platform for a new generation of targeted cancer diagnostics and therapies. Furthermore, ITM is developing a proprietary portfolio and growing pipeline of targeted treatments in various stages of clinical development addressing a range of cancers such as neuroendocrine cancers or bone metastases. ITM's main objectives, together with its scientific, medical and industrial collaboration partners worldwide, are to significantly improve outcomes and quality of life for cancer patients while at the same time reducing side-effects and improving health economics through a new generation of TRT in Precision Oncology.
For more information about ITM, please visit: www.itm.ag

References

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