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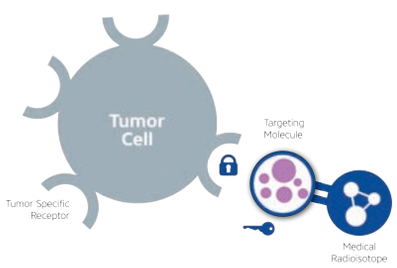
Radiant Precision by ITM

Highly-precise Targeted Radionuclide Therapy – a promising new generation of targeted molecular therapy in which smallest amounts of medical radioactivity in the form of radiopharmaceuticals find their way through the bloodstream specifically targeting tumor cells for diagnosis and treatment of cancer. ITM develops, produces and distributes worldwide a new generation of radiopharmaceuticals for Targeted Radionuclide Therapy.

Since Marie Curie, radiation research has been fundamental in the development of Nuclear Medicine. Furthermore, biomedical investigations on various tumor markers have contributed to the evolution of Precision Oncology, paving the way for Targeted Radionuclide Therapy (also known as peptide receptor radionuclide therapy / PRRT). In contrast to radiotherapy, where radiation is applied from outside the body, Targeted Radionuclide Therapy is defined by the injection of a radiopharmaceutical which precisely recognizes tumor cells. Radiopharmaceuticals consist of a medical radioisotope conjugated to a tumor-specific targeting molecule that binds specifically to a tumor antigen according to the lock-and-key principle. A very small amount of medical radiation is sufficient for this approach. Due to the precision and specificity of Targeted Radionuclide Therapy, healthy tissue is minimally affected and side effects are maximally reduced. In many cases, the targeting molecule can be used in a so called theranostic approach for both diagnostics and therapy, only differing in their conjugated radioisotope. Radioisotopes with shorter half-lives are used for diagnosis, while therapeutic ones have slightly longer half-lives.



Lock and Key principle of Targeted Radionuclide Therapy.

ITM's Medical Radioisotopes

The biotechnology and radiopharmaceutical group of companies ITM Isotopen Technologien München AG (ITM) develops, produces and distributes worldwide medical radioisotopes and radiopharmaceuticals for Targeted Radionuclide Diagnostics and Therapy in Precision Oncology. ITM has established a method to produce the highly pure no-carrier-added (n.c.a.) Lutetium-177 (^{177}Lu). As opposed to other forms of the Lutetium radioisotope, n.c.a. ^{177}Lu does not contain metastable impurities. Thus, there is no need for cost intensive clinical disposal management. N.c.a. ^{177}Lu can therefore be used globally – including regions facing strict radiation protection regulations. N.c.a. ^{177}Lu has a half-life of 6.647 days and shows a specific activity which is up to six times higher than the specific activity of carrier-added Lutetium. When radiolabeled to tumor-specific targeting molecules, it emits low-energy, cytotoxic β-particles in a maximum radius of 1.7 mm to the tumor tissue. ITM's n.c.a. ^{177}Lu is also known under the brand name Endolucin-Beta®.

Besides β-emitters, α-emitters such as Actinium-225 are currently, due to their short range, emerging in clinical research as important clinical treatment options for micrometastases or leukemia. In 2019, together with the Technical University of Munich (TUM) and with the support of the Bavarian Research Foundation, ITM started the *FORActinium* project with the aim of developing an efficient and industry-scale manufacturing process for the therapeutic radioisotope Actinium-225.
Recently, ITM was honored with the "German Medical Award" and received the prestigious support of the European Investment Bank for their dedicated work on Targeted Radionuclide Diagnostics and Therapies in Precision Oncology. ITM's main goal is to significantly improve the outcome and quality of life of cancer patients to achieve a sustainable medical benefit.

How is ITM pursuing its goal to improve the outcome for cancer patients?
"We are currently conducting the clinical phase III trial COMPETE, which is investigating the efficacy and safety of the therapeutic radiopharmaceutical Solucin®", answers ITM's CEO Steffen Schuster. Solucin® consists of a somatostatin analogue as the targeting molecule and ITM's highly pure n.c.a. ^{177}Lu and is used for the treatment of somatostatin receptor positive neuroendocrine tumors (NET) of gastroenteropancreatic origin. Neuroendocrine tumors fall into the category of rare diseases resulting in a high demand for effective therapies. "We are confident that COMPETE will confirm the promising results of our Phase II study and will give many neuroendocrine tumor patients the opportunity to benefit from this new generation of Targeted Radionuclide Therapy", added Mr. Schuster.

Production of n.c.a. ^{177}Lu-Edotreotide (Solucin®) according to Good Manufacturing Practice (GMP).

ITM's Precision Oncology Pipeline

In addition to Solucin®, ITM is working on further product candidates for diagnosis and therapy of cancer such as osteosarcoma or osteoblastic bone metastases, glioblastoma and folate receptor α positive (FRα$^+$) cancer, which all require innovative alternative treatment options. ITM is thereby actively shaping the progress of radiopharmaceutical research and development – a "radiant" contribution to treating cancer.

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