

Garching, Germany, September 17, 2018

## **ITM and Merck sign Research Evaluation and Option Agreement to develop Folate Receptor Targeted Radionuclide Therapy**

**The companies to combine their technologies to develop novel theranostic radiopharmaceuticals  
Merck to supply folate derivatives for the preparation of folate-based radiotheranostics  
ITM to receive option for worldwide exclusive license for clinical development and commercialization of folate-based radiotheranostics**

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Isotopen Technologien München AG (ITM), a group of specialized radiopharmaceutical companies, announced today that it has signed a Research Evaluation and Option Agreement for a worldwide exclusive license with Merck, Darmstadt, Germany. Merck is a global leader for the development and manufacturing of active pharmaceutical ingredients with particular expertise related to reduced folates. This partnership with Merck will allow for a broader application of ITM's Theranostics platform to include diagnosis and therapy of patients with folate receptor-positive cancers.

The partnership covers the evaluation of Merck first-in-class folate derivatives as radiolabeled diagnostic and therapeutic agents for the treatment of serious oncological folate receptor-positive diseases. Under the agreement ITM receives an option for a worldwide exclusive license for clinical development and commercialization of radiolabeled folate derivatives, while Merck will supply folate precursors for radiolabeling.

Folate receptors are known to be overexpressed by several cancer types, such as ovarian, lung, breast and other types of cancers. The restricted expression of folate receptors to only a few sites in normal tissues makes them an attractive diagnostic and therapeutic target. Folate is a B vitamin that is critical to DNA synthesis as well as other essential cell processes. Folate derivatives retain their receptor binding properties when conjugated to pharmaceuticals. They have been proven to be promising compounds for cancer treatment for quite some time and therefore represent an outstanding addition to ITM's Targeted Radionuclide Therapy pipeline.

In folate receptor targeting, the folate moiety of the folate-based radiopharmaceutical acts as targeting molecule for both diagnosis and therapy. The radiopharmaceutical is injected into the patient's body, where it binds to the corresponding receptors on the tumor tissue. The radio-conjugate is then absorbed by the tumor cells. For diagnostic application, medical radioisotopes with short half-lives, like Gallium-68, are combined with the targeting molecule. With highly sensitive molecular imaging technologies like PET (Positron Emission Tomography), whole-body diagnostic images are created. For targeted treatment, folate derivatives are complexed with medical radioisotopes with longer half-lives, like ITM's highly pure no-carrier-added Lutetium-177. The availability of folate receptor-targeted radiopharmaceuticals for both diagnosis and therapy opens up the way for radiotheranostic applications in various indications.

Dr Matthias Joehnck, Head of R&D Actives and Formulation, Merck, said: *"The use of radiolabeled compounds for diagnosis or therapy in medicine is an intensively developing field. We are pleased that our technology will serve to advance a new and promising approach for cancer treatment."*

*"We are very delighted to have access to the outstanding technology and expertise of Merck in the area of pharmaceutical chemistry and manufacturing of folate-based compounds,"* Steffen Schuster, Chief Executive Officer of ITM, added, *"Merck has deep expertise in derivatization chemistry of Folic Acid and manufacturing of GMP grade folates. Their expertise, in combination with our innovative platform-technology, will help us to achieve new milestones in Targeted Radionuclide Therapy."*

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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, like cancer. Targeted radiopharmaceuticals contain 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 to a tumor-specific receptor or antigen, 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 used. 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 therefore be diagnosed in their early stages. Medical radioisotopes with longer half-lives are applied for treatment. The tumor tissue is being destroyed by the radiopharmaceutical emitting cytotoxic doses of ionizing radiation. A highly precise localization of the radioactivity ensures that healthy tissue in the surroundings of the targeted tumor is minimally affected.

### **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 GMP manufacturing and a robust global supply network of 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, which address 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 Targeted Radionuclide Therapies in Precision Oncology.

For more information about ITM, please visit: [www.itm.ag](http://www.itm.ag)

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