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Plattform Life Sciences

Technologie – Finanzierung – Investment

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Investing in Life Sciences

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lacked glamour

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Bridging the Gap Between Diagnosis and Therapy: Theranostics

ITM – leveraging the full potential of nuclear medicine for cancer patients

A great deal has happened since 2004, when ITM Isotopen Technologien München AG, a privately owned company, was founded in the shadow of the Technical University of Munich (TUM) research reactor, also known as the “Atomic Egg.” Originally a radioisotope manufacturer, ITM has in time not only established a renowned global supply network of innovative high-quality medical radioisotopes but has also developed a proprietary pipeline of high-precision radiotherapeutics and diagnostics. In doing so, the company is well-positioned to take the growing field of personalized cancer medicine by storm. **By Dr Georg Kääh**

A brief glimpse into the field of radiation physics clarifies the company’s approach. Gamma rays (“soft rays”), which are not harmful to tissue, are used for the diagnostic imaging and detection of cancer. Treatment is conducted by applying slightly stronger, targeted beta-emitters which destroy the cancer cells without causing collateral damage to surrounding healthy tissue. By combining a suitable tumor-specific targeting molecule as a biomarker with the radioisotope in question, the approach can be applied and adapted to both diagnosis and treatment. Therapy and diagnosis are therefore combined at the molecular level in a highly specific and targeted manner, leading to the creation of the term “theranostics.”

Treatment with radioisotopes

Since 2009, ITM has concentrated on the development of its lead product, the highly pure therapeutic radioisotope no-carrier-added (n.c.a.) Lutetium-177, which was granted marketing authorization by the European Medicines Agency

ITM ISOTOPEN TECHNOLOGIEN MÜNCHEN AG

Founded: 2004

Location: Garching near Munich

CEO: Steffen Schuster

Workforce: 300

Segment: Cancer diagnostics and therapeutics

Web: www.itm.ag



Photo: © ITM Isotopen Technologien München AG

(EMA) in 2016 and issued a Drug Master File by the US Foods and Drug Administration (FDA). N.c.a. ¹⁷⁷Lu is also known under the brand name EndolucinBeta[®]. 2010 saw the production start of the next generation Germanium-68/Gallium-68 generator, which creates Gallium-68, a radioisotope for tumor diagnostics, for use in molecular imaging with PET/CT/MRI. In order to function as a radiopharmaceutical “one-stop shop,” ITM also produces all the equipment necessary to use and process diagnostic and therapeutic radioisotopes. The company also works in close cooperation with an international network of experts and medical professionals to continually evaluate other alpha- or beta-emitters for use as therapeutic radioisotopes.

A promising pipeline

The first product candidate from the in-house precision oncology pipeline is currently being tested in the international

phase III clinical trial, COMPETE. This study is evaluating the efficacy and safety of Targeted Radionuclide Therapy with n.c.a. ¹⁷⁷Lu-Edotreotide as the therapeutic radiopharmaceutical for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs). This means that a therapeutic product with the potential to considerably improve treatment outcome and quality of life for patients living with this difficult-to-treat cancer is on the path toward market approval.

In 2018, ITM took another important step towards a new generation of theranostics for NETs with TOCscan[®] (68Ga-Edotreotide). TOCscan[®] is the diagnostic companion to n.c.a. ¹⁷⁷Lu-Edotreotide and a ready-to-use radiopharmaceutical that enables high-quality PET images to precisely localize tumors. Marketing authorization has already been granted in Germany, Austria, and France.

A special role in personalized medicine

ITM, now comprised of 300 employees, has a unique position in the field of personalized medicine. In particular, with its rapidly growing precision oncology pipeline, the company is extending its international presence.

This strong growth strategy is reflected not only in the signing of several major radioisotope production and supply agreements but also in the opening of new production sites. Together with leading partners, the pipeline is being extended to encompass promising new candidates for various indications,

including neuroendocrine tumors, glioblastoma, osteosarcoma and bone metastases, as well as folate receptor -positive tumors such as lung, ovarian, and breast cancer. ITM is another prime example of pioneering biotechnology companies emerging in Germany. ■

“In my opinion, precision oncology is one of the most exciting fields in personalized medicine”

Interview with Udo J Vetter*, Chairman of the Supervisory Board, ITM Isotopen Technologien München

Plattform Life Sciences: Are you a “first-round” investor? What was it about ITM’s vision that appealed to you?

Vetter: Right from the start, I’ve been very impressed by the strong focus on patient benefit and the enormous dedication of all ITM employees. The high quality of the products, the immense specialized know-how, and ITM’s spirit of innovation – especially regarding its growing precision oncology pipeline – are further aspects that I value highly and to which we at UV-Cap are also committed. ITM’s mission to improve the lives and treatment outcomes of cancer patients by developing new therapeutic options brings the whole team together. This strong motivation and determination to bring precision cancer therapy to the next level are key success factors making ITM exceptional.

With the billion-dollar acquisitions of AAA and Endocyte by Novartis, the field suddenly gained attention a few years ago. Where is ITM now on the international radar?

With outstanding quality medical radioisotopes and its global logistics and distri-

bution network, ITM has already made a name for itself worldwide and established itself as a leading company on the international market. ITM also supplies big pharma companies for their development of therapeutic candidates for the treatment of various cancers. With this starting position and the expertise in radioisotope development, manufacturing, and distribution gained over almost two decades, the transformation into a radiopharmaceutical biotech company with its own oncology pipeline is the next logical step. Here, the ITM team is further supported by its broad network of international partners. The orphan drug status granted by the EMA and FDA to its therapeutic lead candidate and the ongoing international phase III clinical trial underline the huge potential of ITM’s precision oncology pipeline.

One challenge of radiopharmacy is the at times ultrashort half-life of the emitter, which requires a special logistic effort. What is ITM’s international strategy in this respect?

Besides our widely branching global logistics and distribution network, we also have a special production strategy for our radioisotopes that allows the customer, when ordering, to indicate in advance the activity required for the day of application. Furthermore, we are continuously working to expand our production capacity and facilities worldwide.

As an investor, you have an overview of the market and its potential. In your

opinion, what is it that makes ITM such a promising investment opportunity?

With its portfolio of market-leading radioisotopes, global distribution network and promising pipeline, ITM has a unique combination of the best prerequisites for further successful growth. Additionally, in my opinion, precision oncology is one of the most exciting fields of personalized medicine, with a high market potential. Here, I see great chances of success for ITM’s Targeted Radionuclide Therapy, particularly in offering new treatment options to patients with difficult-to-treat or refractory cancer.

Mr. Vetter, thank you very much for the interesting interview. ■

The interview was conducted by Dr Georg Käbb.



Udo J Vetter

*) Udo J Vetter has been the chairman of the supervisory board at ITM since 2007; he represents one of ITM’s main investors, UV-Cap GmbH & Co KG, which he founded. A pharmacist graduating from the University of Washington, Udo J Vetter has been managing director of several pharmaceutical companies in the course of his entrepreneurial career. He is also a member of the supervisory and advisory boards of various innovative companies and institutions, including Vetter Pharma, one of the world’s leading pharmaceutical service providers for sterile filling and packaging of syringes and other injection devices.