Garching, November 14, 2017

Successful Hosting of the Investigator Meeting for Phase III Clinical Trial COMPETE with n.c.a.^{177}Lu-Edotreotide (Solucin®) in Cancer Patients with GEP-NET

ITM's subsidiary ITM Solucin lead 2-day-event focused on study update and efficient trial execution
Meeting attended by over 60 investigators as well as study nurses from 30 leading cancer centers in 10 countries

ITM Isotopen Technologien München AG (ITM), a specialized radiopharmaceutical company, today announced that ITM's subsidiary ITM Solucin was successfully hosting an investigator meeting for its phase III clinical trial COMPETE on October 25-26, 2017 in Vienna, Austria.

The COMPETE clinical trial is an international multi-center phase III clinical study evaluating the efficacy and safety of Targeted Radionuclide Therapy with n.c.a.^{177}Lu-Edotreotide (Solucin®) compared to Everolimus in patients with inoperable, progressive, somatostatin-receptor positive neuroendocrine tumors of gastroenteric or pancreatic origin (GEP-NET), started in Australia in April of this year.

ITM Solucin managed to gather over 60 investigators either in the field of nuclear medicine or medical oncology as well as study nurses from 30 leading cancer centers located in 10 countries. The investigator meeting functioned as an informative assembly, in which the participants found out detailed information about all aspects of the COMPETE study and had the opportunity to ask questions and discuss potential topics. A keynote lecture was held by Professor Martyn Caplin, Royal Free London & University College London, on "The Role of PRRT (Peptide Receptor Radionuclide Therapy) in the Treatment Algorithm of NET - Questions to be answered".

GEP-NETs are considered as a rare disease with a complex development as well as a poor forecast. There are only few suitable and well tolerated treatment options, where prospective clinical trials with radiopharmaceuticals are limited. These facts strengthen the importance of the COMPETE clinical trial, which would make a significant contribution to treatment outcomes, therefore, improving the quality of life for cancer patients.

Steffen Schuster, CEO of ITM commented: *"In collaboration with leading Oncological and Nuclear Medicine physicians of ENETS we have created a phase III clinical trial with a well-considered approach to create prospective scientific data of high quality targeting the broad indication of non-functional GE-NET /functional or non-functional P-NET thereby using the standard of care Everolimus as comparator. I am happy to say that the investigator meeting was a great success."* He added: *"Thanks again to all participants for the motivation and active engagement in bringing a new promising therapy to market and to the patients."*

- Ends -

About COMPETE
The phase III clinical trial COMPETE is led as an international, prospective, randomized, controlled, open-label, multicenter phase III study to evaluate efficacy and safety of Targeted Radionuclide Therapy with n.c.a. ^{177}Lu-Edotreotide (Solucin®) compared to targeted molecular therapy with Everolimus in patients with inoperable, progressive, somatostatin receptor-positive ($SSTR^{+}$) neuroendocrine tumors of gastroenteric or pancreatic origin (GEP-NET). The trial, which is carried out in collaboration with the Clinical Research Organization ABX-CRO advanced pharmaceutical services Forschungsgesellschaft mbH, will be conducted worldwide in 11 countries and 35 sites.

In total, 300 GEP-NET patients will be randomized 2:1 to receive either Targeted Radionuclide Therapy with Solucin® consisting of a maximum of four cycles (7.5 GBq ^{177}Lu-Edotreotide each), administered as i.v. infusion at 3-monthly intervals for 9 months, or until diagnosis of progression (200 patients), or 10 mg Everolimus daily, administered orally as a tablet until diagnosis of progression (100 patients). Study duration per patient will be 24 months.

Primary endpoint is progression-free survival (PFS). Diagnosis of progression and liver tumor burden will be established based on radiological information from morphological imaging (MRI and/or CT) according to RECIST 1. Secondary endpoints include overall survival (OS), parameters of morphological and functional tumor response, safety and health-related quality of life (HRQL). Furthermore, patient and tumor characteristics, as well as the uptake of n.c.a. ^{177}Lu-Edotreotide will be exploratively analyzed for traits predicting Targeted Radionuclide Therapy efficacy.
For more information about the COMPETE study please visit: www.compete-clinical-trial.com

About Targeted Radionuclide Therapy
Targeted Radionuclide Therapy is a medical specialty using 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), pictures 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. To destroy the tumor, minimal cytotoxic doses of ionizing radiation have to be administered to the tumor site before decay. A highly precise localization of the radioactivity ensures that healthy tissue in the surroundings of the targeted tumor is minimally affected.

About Solucin®
Solucin® (n.c.a. ^{177}Lu-Edotreotide / n.c.a. ^{177}Lu-DOTATOC) is known as an innovative Targeted Radionuclide Therapy agent with favorable safety profile and promising efficacy. Solucin® consists of two molecular components – firstly of Edotreotide (DOTATOC), an octreotide-derived somatostatin analogue, and secondly, of EndolucinBeta (no-carrier-added Lutetium-177) a synthetic, low-energy beta-emitting isotope of Lutetium.

The targeting molecule Edotreotide (DOTATOC) contains DOTA which functions as a chelator for radioisotopes and TOC, a synthetic somatostatin receptor ligand. It binds with high affinity somatostatin receptors (subtype 2 and 3) and retains both its receptor binding properties and its physiological function when labeled with ^{177}Lu. Somatostatin receptors type 2 (SSTR2) are predominantly overexpressed by neuroendocrine tumors. Solucin®, upon binding to SSTR2 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 in Targeted Radionuclide Therapy, e.g. in the field of Precision Oncology. 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 recently received marketing authorization in the EU.
For more information about Solucin® please visit: www.compete-clinical-trial.com

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 Targeted Radionuclide Therapies in Precision Oncology.

ITM Isotopen Technologien München AG is front-runner in the life sciences industry of Germany's fastest growing technology companies. With 174 % growth, ITM was granted with the Deloitte Technology Fast 50 Award in 2017.

For more information about ITM, please visit: www.itm.ag

ITM Isotopen Technologien München AG
Contact
Nicola Scharrer
Head of Marketing
Phone: +49 89 3298986-16
Mail: Nicola.Scharrer@itm.ag

Media Contact: WE Communications
Stephanie Kunz
Account Director
Phone: +49 89 628175-19
Mail: ITM_AG@we-worldwide.com