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ITM and DCB sign exclusive Licensing & Development Agreement for Solucin® TRT in South Korea while COMPETE clinical trial sees strong growth in recruitment numbers in the U.S.

ITM Isotopen Technologien München AG (ITM), a biotechnology and radiopharmaceutical group of companies, and DuChemBio Co, Ltd. (DCB), a leading Korean radiopharmaceutical company, announced today the conclusion of an exclusive licensing and development agreement for Solucin® Targeted Radionuclide Therapy (TRT) in South Korea. The agreement sets out terms concerning the local development, registration and subsequent commercialization by DCB of ITM's proprietary brand Solucin® for Targeted Radionuclide Therapy (TRT) in South Korea. Solucin® patient doses will be manufactured and exclusively supplied to DCB by ITM.

Within the framework of this collaboration, DCB and ITM plan to initiate a local clinical study for ITM's Solucin® TRT which is expected to begin recruiting patients in 2020. The study concept is based on ITM's Phase III clinical trial COMPETE, which has recently seen a considerable increase in patients as a result of strong recruitment in the United States in particular. COMPETE involves 42 leading cancer centers in 12 countries, predominantly in Europe, North America, South Africa and Australia.

The COMPETE clinical trial is an international multi-center phase III clinical study evaluating the efficacy and safety of Targeted Radionuclide Therapy with no-carrier-added Lutetium-177-Edotreotide (Solucin®). Its aim is to compare Solucin® to Everolimus in patients with inoperable, progressive, somatostatin-receptor positive neuroendocrine tumors of gastroenteric or pancreatic origin (GEP-NET). The study's primary endpoint is progression-free survival (PFS).

"We are very excited about our partnership with DuChemBio," said Steffen Schuster, CEO of ITM. *"The strong growth in patients recruited for our phase III clinical trial COMPETE in the recent months emphasizes the demand for effective treatment options for GEP-NET patients worldwide. In DCB we have found a reliable partner that is as committed as we are, to improving the outcome and quality of life for cancer patients. Together we want to establish Targeted Radionuclide Therapy as an alternative for cancer patients in South Korea."*

"Duchembio is delighted to enter this partnership with ITM as a next step to expand our product portfolio into the Theranostics domain" said Jong-Woo Kim, President and CEO of DCB. "Whilst Duchembio - via its Nuc. Med. customers across the country - already supports the diagnosis of GEP-NET patients by means of PET imaging, the inclusion of an innovative radioligand therapy like Solucin® TRT in DCB's portfolio now provides a comprehensive solution for Korea's leading cancer centers to manage GEP-NET patients."

Solucin® is a TRT agent, which consists of the targeting molecule Edotreotide, an octreotide-derived somatostatin analogue and ITM´s EndolucinBeta® (n.c.a. ^{177}Lu). The radiopharmaceutical is administered as an intravenous infusion, specifically targeting and destroying the tumor cells in-situ with ionizing radiation.

In South Korea some 400-450 patients are diagnosed with GEP-NET every year. Treatment options are limited and Solucin® PRRT will offer an alternative to patients with inoperable and progressive disease. DCB also intends to initiate a Compassionate Use Program (CUP) during the phase II local clinical trial to make Solucin® TRT patient doses available to additional Korean patients suffering from GEP-NET.

– Ends –

About COMPETE phase III clinical trial
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 TRT with n.c.a. 177Lu-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 is conducted worldwide in 12 countries and 42 leading cancer centers, predominantly in Europe, North America, Australia and South Africa.

In total, 300 GEP-NET patients will be randomized 2:1 to receive either TRT with Solucin® consisting of a maximum of four cycles (7.5 GBq 177Lu-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 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. 177Lu-Edotreotide will be analyzed for criteria predicting the efficacy and safety of TRT.

About Solucin®
Solucin® (n.c.a. 177Lu-Edotreotide / n.c.a. ^{177}Lu-DOTATOC) is known as an innovative TRT 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, medium-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 5) and retains both its receptor binding properties and its physiological function when labeled with ^{177}Lu. Somatostatin receptors type 2 (SSTR2) are predominantly over-expressed by neuroendocrine tumors. Solucin®, upon binding to SSTR2 receptors in-situ 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 TRT, 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.

About ITM Isotopen Technologien München
ITM Isotopen Technologien München AG is a privately held biotechnology and radiopharmaceutical group of companies dedicated to the development, production and global supply of targeted diagnostic and therapeutic radiopharmaceuticals and radionuclides for use in cancer treatment. 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 tumors and 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.

About DCB
Established in 2002, DuChemBio is the largest radiopharmaceutical firm and the leading supplier of oncology and neurology molecular imaging products in South Korea. As a pioneer of a fully integrated nuclear diagnostics business model, DCB develops, manufactures, and commercializes radiopharmaceutical tracers for PET/CT and PET/MRI hybrid imaging. The company operates 7 radio-pharmacy facilities across the country, is closely collaborating with leading hospitals and research centers in Seoul to develop and advance the field of nuclear medicine in South Korea. DCB has successfully launched novel proprietary radiopharmaceutical products both developed locally and licensed from international partners.

Duchembio has been advised by BGM Associates GmbH, a Berlin-based strategy and transactions advisory firm focused on healthcare and life science industries.

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