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ITM, DCB sign agreement for Targeted Radionuclide Therapy

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The agreement sets out terms concerning the local development, registration and subsequent commercialization by DCB of ITM's proprietary brand SolucinÃ?Â® for Targeted Radionuclide Therapy (TRT)



ITM Isotopen Technologien München AG (ITM), a biotechnology and radiopharmaceutical group of companies, and DuChemBio Co, Ltd. (DCB), a leading Korean radiopharmaceutical company, announced, on 2nd Sep 2019, 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 centres in 12 countries, predominantly in Europe, North America, South Africa and Australia.

The COMPETE clinical trial is an international multi-centre 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 tumours 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 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 improve 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 support 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 centres 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 tumour 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.