

ITM Announces Successful Completion of Patient Recruitment for its Phase III Trial, COMPETE, with Lead Radiotherapeutic ITM-11 (n.c.a. ¹⁷⁷Lu-edotreotide)

Garching / Munich, April 11, 2022 – [ITM Isotope Technologies Munich SE \(ITM\)](#), a leading radiopharmaceutical biotech company, today announced the randomization of the 300th patient and thus the successful completion of patient recruitment in its phase III clinical trial COMPETE, evaluating the efficacy and safety of its lead Targeted Radionuclide Therapy candidate, [ITM-11](#) (n.c.a. ¹⁷⁷Lu-edotreotide), in grade 1 and 2 gastroenteropancreatic neuroendocrine tumors (GEP-NETs). Completing patient recruitment is an important milestone demonstrating the progress of the COMPETE study, with which ITM aims to prove the potential of its therapeutic approach to provide added value to patients with GEP-NETs by improving both, treatment outcomes and the patient’s quality of life.

GEP-NETs are rare types of tumors originating in the pancreas or other parts of the gastrointestinal tract. Due to their heterogeneity and unique characteristics, diagnosing GEP-NETs early is difficult, increasing the likelihood of metastatic disease and severely limiting treatment options. With ITM-11, the company is striving to address the existing unmet need, providing patients options with an effective approach to treating these life-threatening tumors. This goal is supported by results from previous studies and compassionate use, which suggest a high potential for this therapeutic approach. To further broaden its reach, ITM-11 is also being evaluated in a second phase III trial, COMPOSE, for patients with high grade 2 and grade 3 GEP-NETs.

“Targeted Radionuclide Therapy with ITM-11, may provide an effective and well tolerated treatment option for patients with GEP-NETs, who have a high unmet medical need. This highly targeted, precise approach minimizes radiation exposure of surrounding healthy tissue and helps to maintain quality of life during treatment,” commented Prof. Jaume Capdevila, Principal Investigator of COMPETE at the University Hospital Vall d’Hebron in Barcelona, Spain. *“We look forward to collecting further data from the study and evaluating ITM-11 in this large patient population.”*

“This is a very important step forward for ITM as our lead candidate continues through the final stages of the clinical trial,” added Steffen Schuster, CEO of ITM. *“Completing patient recruitment for COMPETE underscores the progress of our broad proprietary pipeline of radiopharmaceuticals which we hope will improve the lives of patients living with solid tumors and severely limited treatment options such as GEP-NETs. With our research and clinical studies, we strive to meet the needs of a patient population that could benefit from precision oncology treatments.”*

COMPETE ([NCT03049189](#)) is an international, prospective, randomized, controlled, open-label, multi-center phase III study to evaluate the efficacy and safety, of Targeted Radionuclide Therapy with ITM-11 (n.c.a. ¹⁷⁷Lu-edotreotide) compared to targeted molecular therapy with everolimus in patients with inoperable, progressive, grade 1 and 2, somatostatin receptor-positive (SSTR⁺) neuroendocrine tumors of gastroenteric or pancreatic origin. The study has randomized 300 patients across multiple participating study sites worldwide. The primary endpoint of the study is progression-free survival (PFS), and secondary outcome measures include overall survival (OS).

The [COMPETE study design](#) was presented at the AACR annual meeting 2021. ITM’s second phase III trial with ITM-11 for grade 2 and 3 GEP-NETs, COMPOSE ([NCT04919226](#)), is ongoing and was [introduced at the 2021 North American Neuroendocrine Society \(NANETS\) symposium](#) as well as at the [2022 ASCO Gastrointestinal Cancers Symposium](#) (ASCO-GI). Sponsor of both studies is ITM’s subsidiary ITM Solucin GmbH.

About Targeted Radionuclide Therapy

Targeted Radionuclide Therapy is an emerging class of cancer therapeutics, which seeks to deliver radiation directly to the tumor while minimizing radiation exposure to normal tissue. Targeted radiopharmaceuticals are created by linking a therapeutic radioisotope to a targeting molecule (e.g., peptide, antibody, small molecule) that can precisely recognize tumor cells and bind to tumor-specific characteristics, such as receptors on the tumor cell surface. As a result, the radioisotope accumulates at the tumor site and decays, releasing a small amount of ionizing radiation, thereby destroying tumor tissue. The highly precise localization enables targeted treatment with minimal impact to healthy surrounding tissue.

About ITM-11 (n.c.a. ¹⁷⁷Lu-edotreotide)

ITM-11, ITM's therapeutic radiopharmaceutical candidate being investigated in the phase III clinical studies COMPETE and COMPOSE, consists of two components: the medical radioisotope no-carrier-added lutetium-177 (n.c.a. ¹⁷⁷Lu) and the targeting molecule edotreotide, a synthetic form of the peptide hormone somatostatin that targets neuroendocrine tumor-specific receptors. Edotreotide binds to these receptors and places the medical radioisotope n.c.a. lutetium-177 directly onto the diseased neuroendocrine cells so that it accumulates at the tumor site. N.c.a. lutetium-177 is internalized into the tumor cells and decays, releasing medical radiation (ionizing β -radiation) with a maximum radius of 1.7 mm and destroying tumor tissue. The highly precise localization can result in the healthy tissue surrounding the targeted tumor being minimally affected.

ITM Isotope Technologies Munich SE

ITM, a leading radiopharmaceutical biotech company, is dedicated to providing a new generation of radiomolecular precision therapeutics and diagnostics for hard-to-treat tumors. We aim to meet the needs of cancer patients, clinicians and our partners through excellence in development, production and global supply. With improved patient benefit as the driving principle for all we do, ITM advances a broad precision oncology pipeline, including two phase III studies, combining the company's high-quality radioisotopes with a range of targeting molecules. By leveraging our nearly two decades of pioneering radiopharma expertise, central industry position and established global network, ITM strives to provide patients with more effective targeted treatment to improve clinical outcome and quality of life. www.itm-radiopharma.com

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