ITM Announces First Patient Treated in Second Phase III Trial, COMPOSE, with ITM-11 (n.c.a. ^{177}Lu-edotreotide) for Treatment of Neuroendocrine Tumors

Garching / Munich, January 25, 2022 – ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company, today announced that the first patient has been treated in its second pivotal phase III clinical trial, COMPOSE (NCT04919226), evaluating the company's lead radiopharmaceutical candidate, ITM-11 (n.c.a. ^{177}Lu-edotreotide), for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs). ITM-11 is a Targeted Radionuclide Therapeutic consisting of the high-quality radioisotope no-carrier-added lutetium-177 (n.c.a. ^{177}Lu) fused with a somatostatin analogue to specifically target somatostatin receptor-positive (SSTR$^+$) GEP-NETs. While COMPOSE is evaluating ITM-11 for the treatment of well-differentiated high grade 2 and grade 3 GEP-NETs, the radiopharmaceutical is also being investigated in ITM's ongoing pivotal phase III trial, COMPETE (NCT03049189), in patients with grade 1 and 2 GEP-NETs. GEP-NETs are rare types of tumors that can occur in the pancreas or in other parts of the gastrointestinal tract. Due to their frequent asymptomatic and progressive nature, GEP-NETs often present late with advanced disease requiring innovative therapeutic measures. The trial design of COMPOSE was recently presented at the 2022 ASCO Gastrointestinal Cancers Symposium (ASCO-GI) and the 2021 North American Neuroendocrine Tumor Society (NANETS) annual symposium.

"*We are committed to providing urgently needed solutions for the treatment of GEP-NETs which are often diagnosed with advanced disease,"* commented Steffen Schuster, Chief Executive Officer of ITM. *"As such, we hope to build upon previous promising data to demonstrate in COMPETE and COMPOSE that Targeted Radionuclide Therapy with ITM-11 has the potential to improve treatment outcomes and quality of life for a broad patient population."*

"Targeted Radionuclide Therapy is a promising therapeutic concept that enables a precise intervention both for the primary tumor as well as for metastases. N.c.a. ^{177}Lu-edotreotide has demonstrated potential in earlier stage GEP-NET patients, and I look forward to evaluating it in a more advanced late-stage population with higher tumor grade in high need of better therapeutic options," added Prof. Walter, Principal Investigator of COMPOSE at Hospices civils de Lyon, France.

COMPOSE (NCT04919226) is an international, prospective, randomized, controlled, open-label, multi-center phase III clinical trial to evaluate the efficacy, safety, and patient-reported outcomes of first- or second-line treatment with ITM-11 (n.c.a. ^{177}Lu-edotreotide) compared to best standard of care in patients with well-differentiated high grade 2 and grade 3 (Ki-67 index 15-55), SSTR$^+$, GEP-NETs. The study aims to randomize 202 patients 1:1 to ITM-11 or to best standard of care — either chemotherapy (CAPTEM or FOLFOX) or everolimus — according to the investigator's choice. The primary endpoint of the study is progression-free survival, which will be assessed every 12 weeks from randomization onwards. Secondary outcome measures include overall survival up to two years after disease progression. Sponsor of the COMPOSE trial is ITM Solucin GmbH, a subsidiary of ITM Isotope Technologies Munich SE.

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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. ^{177}Lu-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. ^{177}Lu) 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 radiopharmaceutical biotech company, is dedicated to providing the most precise cancer radiotherapeutics and diagnostics to meet the needs of patients, clinicians and our partners through excellence in development, production and global supply. With patient benefit as the driving principle for all we do, ITM is advancing a broad pipeline, including two phase III studies, combining its high-quality radioisotopes with targeting molecules to develop precision oncology treatments. ITM is leveraging its leadership and nearly two decades of radiopharma expertise combined with its worldwide network to enable nuclear medicine to reach its full potential for helping patients live longer and better.

For more information please visit: www.itm-radiopharma.com.

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