ITM Presents Study Design of COMPOSE Phase III Trial with ITM-11 (n.c.a. ^{177}Lu-edotreotide) for Treatment of Neuroendocrine Tumors at ASCO-GI

Garching / Munich, January 19, 2022 – ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company, today announced the presentation of the study design for its phase III trial, COMPOSE (NCT04919226), at the ASCO Gastrointestinal Cancers Symposium (ASCO-GI), held from January 20 – 22, 2022. COMPOSE will evaluate the company's lead radiopharmaceutical candidate, 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 somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (G2+G3 SSTR$^+$ GEP-NETs). ITM-11 consists of the high-quality radioisotope, no-carrier-added lutetium-177 (n.c.a. ^{177}Lu) chelated to the somatostatin analogue edotreotide. The aim of the study, in which patients are currently being randomized, is to evaluate the efficacy and safety of the Targeted Radionuclide Therapy in this high-need indication. COMPOSE is ITM's second phase III trial with ITM-11 following and building upon COMPETE (NCT03049189), in patients with grade 1 and grade 2 GEP-NETs. Sponsor of the COMPOSE study is ITM's subsidiary ITM Solucin GmbH.

"We look forward to presenting the study design of COMPOSE to the medical and scientific community at ASCO-GI given the significant potential of ITM-11 as an innovative treatment modality," commented Philip E. Harris, MD PhD, Chief Medical Officer at ITM. *"The favorable safety profile and efficacy signals observed to-date with our lead candidate give us reason to believe that ITM-11 can provide an important clinical benefit to patients diagnosed with this high-need indication and an advanced stage of this cancer."*

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 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 (PFS), which will be assessed every 12 weeks from randomization onwards. Secondary outcome measures include overall survival (OS) up to two years after disease progression.

"With poor prognoses and limited treatment options for GEP-NETs, COMPOSE is an important step toward addressing a patient population with a high unmet medical need," commented Thorvardur Ragnar Halfdanarson, Principal Investigator of COMPOSE at the Mayo Clinic, Rochester, MN, USA. *"Targeted Radionuclide Therapy continues to demonstrate promise for the treatment of hard-to-treat tumors. As such, I look forward to investigating its potential for patients with advanced GEP-NETs as we move ITM-11 through this Phase III trial."*

Presentation information

Title: Pivotal phase III COMPOSE trial will compare ^{177}Lu-edotreotide with best standard of care for well-differentiated aggressive grade 2 and grade 3 gastroenteropancreatic neuroendocrine tumor

Abstract No: TPS514

Poster No: P5

Session: Trials in Progress Poster Session B: Pancreas, Small Bowel, and Hepatobiliary Tract

Presenter: Thorvardur Ragnar Halfdanarson, Mayo Clinic, Rochester, MN, USA

- End -

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, like 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.

ITM Contact

Corporate Communications
Julia Hofmann / Susanne Karlsson
Phone: +49 89 329 8986 1502
Email: communications@itm-radiopharma.com

Investor Relations
Ben Orzelek
Phone: +49 89 329 8986 1009
Email: Ben.Orzelek@itm-radiopharma.com

ITM Media Requests

Trophic Communications
Stephanie May or Valeria Fisher
Phone: +49 171 185 56 82
Email: itm@trophic.eu