ITM Presents Design of Second Phase III Trial, COMPOSE, with Radiopharmaceutical ITM-11 for the Treatment of Neuroendocrine Tumors at Annual ENETS Conference 2022

Garching / Munich, March 9, 2022 – ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company, today announced the presentation of the design for its second phase III trial, COMPOSE (NCT04919226) at the 19th Annual European Neuroendocrine Tumor Society (ENETS) Conference being held in a hybrid format in Barcelona on March 10-11, 2022. The study is designed to evaluate the efficacy and safety of ITM's lead radiopharmaceutical candidate, ITM-11 (n.c.a. ^{177}Lu-edotreotide), compared to best standard of care for patients with well-differentiated high grade 2 and grade 3 somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (G2+G3 SSTR$^+$ GEP-NETs). ITM-11 is a Targeted Radionuclide Therapy consisting of the high-quality radioisotope, no-carrier-added lutetium-177 (n.c.a. ^{177}Lu) combined with the somatostatin analogue edotreotide. The poster presentation follows the recent announcement of the first patient treated in the pivotal study.

"ITM is demonstrating its commitment to patients with neuroendocrine tumors expanding its clinical program through the COMPOSE trial with the aim of broadening therapeutic options for patients with high grade GEP-NETs. The potential role of ITM-11 in this area will enable a more personalized approach beyond chemotherapy," said Jorge Hernando, MD, PhD, Medical Oncologist, Vall d´Hebron Institute of Oncology (VHIO), Barcelona, Spain and investigator for COMPOSE. *"I am honored to be presenting ITM´s study design here in Barcelona at this year's ENETS, the most important conference in the neuroendocrine tumors field in Europe – especially now, after two years of online meetings due to COVID-19."*

"Our aspiration with COMPOSE is to demonstrate the value of ITM-11 in more advanced GEP-NET patient populations, as we strive to provide them with better treatment options," stated Steffen Schuster, CEO of ITM. *"We value the opportunity to present our second phase III trial to the expert ENETS community as we continue advancing our lead candidate through the clinic."*

COMPOSE is an international, prospective, randomized, controlled, open-label, multi-center phase III study 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 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. COMPOSE builds upon ITM's first ongoing phase III clinical trial, COMPETE (NCT03049189), examining patients with grade 1 and grade 2, GEP-NETs. ITM's subsidiary, ITM Solucin GmbH is the sponsor of both studies.

Presentation information

Title:	COMPOSE: Phase III Trial of ^{177}Lu-edotreotide versus Standard of Care in Well-differentiated (WD) Aggressive Grade 2 and Grade 3 Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)
Abstract No:	#3389
Poster No:	M03
Session:	Phase III Clinical Trials in Progress
Presenter:	Jorge Hernando, MD, PhD, Vall d'Hebron University Hospital, Barcelona, Spain

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.

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