Garching / Munich, November 03, 2021

ITM Introduces Second Phase III Trial, COMPOSE, with n.c.a. ^{177}Lu-edotreotide for Neuroendocrine Tumors at NANETS Annual Symposium 2021

ITM Isotope Technologies Munich SE today announced the presentation of the design of its new phase III trial, COMPOSE, with the radiopharmaceutical candidate n.c.a. ^{177}Lu-edotreotide in patients with well-differentiated aggressive grade 2 and grade 3 somatostatin receptor-positive gastro-enteropancreatic neuroendocrine tumors (GEP-NETs) at the North American Neuroendocrine Society (NANETS) annual symposium 2021, held virtually from November 3 – 6, 2021. COMPOSE is ITM's second phase III trial with its lead candidate n.c.a. ^{177}Lu-edotreotide, a Targeted Radionuclide Therapy consisting of the high-quality radioisotope no-carrier-added lutetium-177 fused with an innovative somatostatin analogue to specifically target GEP-NETs. N.c.a. ^{177}Lu-edotreotide is also currently being investigated in an ongoing phase III study, COMPETE, in patients with grade 1 and 2 GEP-NETs.

"The most common form of NETs is gastroenteropancreatic and often develops metastatic disease, limiting treatment options. N.c.a. ^{177}Lu-edotreotide has previously shown a favorable safety and efficacy profile in GEP-NETs and with COMPOSE we aim to also make it available to late-stage patients suffering from this hard-to-treat cancer indication," stated Steffen Schuster, CEO of ITM. *"We look forward to the opportunity of introducing our phase III COMPOSE trial to the global scientific community at the NANETS symposium, a key oncology event that features leading research, education, and emerging practices on NETs."*

COMPOSE (NCT04919226) 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 n.c.a. ^{177}Lu-edotreotide PRRT compared to best standard of care in patients with well-differentiated aggressive grade 2 and grade 3 (Ki-67 index 15-55), somatostatin receptor-positive (SSTR$^+$), GEP-NETs. The study aims to randomize 202 patients 1:1 to n.c.a. ^{177}Lu-edotreotide or to an active comparator — 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.

Presentation information

Title:	COMPOSE: Pivotal phase III trial of ^{177}Lu-edotreotide versus best standard of care in well-differentiated aggressive grade 2 and grade 3 gastroenteropancreatic neuroendocrine tumors
Abstract No:	136
Poster No:	410
Session:	Phase III Clinical Trials in Progress
Presenter:	Prof. Thorvardur Halfdanarson, Mayo Clinic, Rochester, MN, USA

For more information on COMPOSE and ITM, visit the ITM virtual booth at the NANETS virtual industry exhibition.

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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, 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 the tumor. The highly precise localization enables targeted treatment with minimal impact to healthy surrounding tissue.

About n.c.a. ^{177}Lu-edotreotide

N.c.a. ^{177}Lu-edotreotide is ITM's therapeutic radiopharmaceutical candidate being investigated in the phase III clinical studies COMPETE and COMPOSE and 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 the tumor. 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 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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