ITM Presents Dosimetry Data from Phase 3 COMPETE Trial Supporting Favorable Efficacy and Safety Profile with n.c.a. ^{177}Lu-edotreotide (ITM-11) in Patients with Gastroenteropancreatic Neuroendocrine Tumors at EANM 2025 Annual Congress

- Study showed targeted tumor uptake with low healthy organ exposure in broad cohort of 207 patients
- Supports therapeutic potential of ITM's proprietary targeted radiotherapeutic agent
- Abstract receives prestigious EANM Marie Curie Award, which honors outstanding research contributions in nuclear medicine

Barcelona, Spain, October 8, 2025 – ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company, today announced dosimetry data from its Phase 3 COMPETE trial in patients with Grade 1 or Grade 2 somatostatin receptor (SSTR)-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) treated with n.c.a. ^{177}Lu-edotreotide (also known as ITM-11 or ^{177}Lu-edotreotide).

Dosimetry, which measures the amount of radiation absorbed by tumors and normal organs, showed that ^{177}Lu-edotreotide delivered targeted radiation to tumors while minimizing exposure to healthy tissue, supporting its favorable efficacy and safety profile. The data were presented by Dr. Emmanuel Deshayes, study investigator and nuclear medicine physician, in an oral presentation at the 38th Annual Congress of the European Association of Nuclear Medicine (EANM), held October 4-8, 2025, in Barcelona, Spain. Dr. Deshayes received the Marie Curie Award, in recognition of exceptional scientific quality and contribution to the field of nuclear medicine at the congress.

As announced in January and March 2025, the Phase 3 COMPETE trial met its primary endpoint, demonstrating a significantly longer median progression-free survival (PFS) in patients treated with investigational agent ^{177}Lu-edotreotide compared to everolimus. A total of 309 patients were randomized to ^{177}Lu-edotreotide (n=207) or everolimus (n=102). Dosimetry evaluations were performed in all patients treated with ^{177}Lu-edotreotide.

In these patients, absorbed dose (AD) for target tumors and all organs besides red bone marrow were measured via whole body planar (2D) and abdominal single-photon emission computed tomography (SPECT) 3D imaging at cycle 1. Red bone marrow dosimetry was performed in a subset of patients (n=20) with additional blood samples at prespecified timepoints to determine the time-activity curves.

Key findings included:

- Absorbed dose in tumors was significantly higher compared to normal organs, supporting therapeutic efficacy and safety
- Normal organ absorbed doses were well below safety thresholds
- Grade ≥1 renal adverse events occurred less often with ^{177}Lu-edotreotide vs. everolimus (14.7% vs. 21.2%)

- The dosimetry assessments are in alignment with the efficacy and safety outcomes of the trial

Tumor Absorbed Dose (AD) is Significantly Higher Than AD to Normal Organs

Mean Cumulative AD - Extrapolated from Cycle 1 (4 cycles x 7.5 GBq injections)	
Tumor	110.0 ± 90.8 Gy
Whole body	0.8 ± 0.6 Gy
Kidneys	12.5 ± 4.4 Gy (assumed safety threshold:23 Gy)
Red bone marrow	0.7 ± 0.4 Gy (assumed safety threshold: 2 Gy)

^{177}Lu-edotreotide Adverse Events Profile in Dose-limiting Organs Compared to Everolimus

	^{177}Lu-edotreotide	**Everolimus**
	Grade ≥1 Adverse events (%)	Grade ≥1 Adverse events (%)
Renal and urinary disorders	14.7 %	21.2 %
Blood and lymphatic disorders	40.1 %	41.4 %

*"*With these data combining extensive dosimetry information from more than 200 patients included in a prospective trial, ITM is laying the groundwork for improved therapeutic decision-making by providing important insights into tumor uptake and treatment variability. It may offer clinically meaningful implications for optimizing individualized patient management," said **Emmanuel Deshayes, MD, PhD, professor in biophysics and nuclear medicine, Montpellier Cancer Institute, France**.

"As the first company to conduct dosimetry in a large, randomized Phase 3 radiopharmaceutical trial in patients with Grade 1 or 2 GEP-NETs, we are encouraged by these findings, which align with the favorable therapeutic and safety profile of ^{177}Lu-edotreotide observed in our COMPETE trial," said **Dr. Andrew Cavey, chief executive officer of ITM**. "This important dosimetry work would not have been possible without the support and cooperation of the investigators and, most importantly, the patients who participated in the trial."

Interim dosimetry data from COMPETE informed the design of ITM's ongoing Phase 3 COMPOSE trial with ITM-11 in well-differentiated, aggressive Grade 2 or Grade 3 SSTR-positive GEP-NET tumors as well as the upcoming Phase 1 pediatric KinLET study in SSTR-positive tumors.

Additional dosimetry data will be presented at future medical congresses.

ITM recently joined the Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium's Precision Dosimetry Imaging Biomarker (PDIB) Project, contributing its dosimetry data to help establish standardized imaging and dosing methods that can improve radiopharmaceutical development and patient outcomes.

EANM Oral Presentation Details

Title: Dosimetry of [^{177}Lu]Lu-edotreotide (ITM-11) in patients with grade 1 or grade 2 gastroenteropancreatic neuroendocrine tumors: Results from the COMPETE Phase 3 trial
Date and Time: October 6, 2025, 3 pm to 3:10 pm CEST

Session and Room Number: #1106 Clinical Oncology Track TROP Session on Gastrointestinal Tumor Imaging
Presenter: Emmanuel Deshayes, MD, PhD, study investigator, associate professor of nuclear medicine at Montpellier Cancer Institute, France

About the COMPETE Trial
The COMPETE trial (NCT03049189) evaluated ^{177}Lu-edotreotide (ITM-11), a proprietary, synthetic, targeted radiotherapeutic investigational agent compared to everolimus, a targeted molecular therapy, in patients with inoperable, progressive Grade 1 or Grade 2 gastroenteropancreatic neuroendocrine tumors (GEP-NETs). This trial met its primary endpoint, with ^{177}Lu-edotreotide demonstrating clinically and statistically significant improvement in progression-free survival (PFS) compared to everolimus. ^{177}Lu-edotreotide is also being evaluated in COMPOSE, a Phase 3 study in patients with well-differentiated, aggressive Grade 2 or Grade 3, SSTR-positive GEP-NET tumors.

About ITM Isotope Technologies Munich SE
ITM, a leading radiopharmaceutical biotech company, is dedicated to providing a new generation of radiopharmaceutical 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 of medical radioisotopes. With improved patient benefit as the driving principle for all we do, ITM advances a broad precision oncology pipeline, including multiple phase 3 studies, combining the company's high-quality radioisotopes with a range of targeting molecules. By leveraging our 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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