ITM Announces Analyses from Phase 3 COMPETE Data Showing Higher Objective Response Rates with n.c.a. ^{177}Lu-edotreotide (ITM-11) vs. Everolimus Across Subgroups of Patients with Gastroenteropancreatic Neuroendocrine Tumors at NANETS 2025 Annual Symposium

Austin, Texas, October 25, 2025 – ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company, announced analyses data from its Phase 3 COMPETE trial in patients with Grade 1 or Grade 2 somatostatin receptor (SSTR)-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs). Results showed consistently higher objective response rates (ORR) and longer progression-free survival (PFS) across subgroups in patients treated with n.c.a. ^{177}Lu-edotreotide (also known as ITM-11 or ^{177}Lu-edotreotide) compared to everolimus, reinforcing its previously reported efficacy profile. Data were shared by study investigator, Jaume Capdevila, MD, PhD, in both oral and poster presentations at the 2025 North American Neuroendocrine Tumor Society (NANETS) Annual Multidisciplinary NET Medical Symposium, held October 23-25, 2025, in Austin, Texas.

As previously announced at ENETS 2025, the COMPETE trial, which included a total of 309 patients randomized to either ^{177}Lu-edotreotide (n=207) or everolimus (n=102), met its primary endpoint of progression-free survival, or PFS, (23.9 vs. 14.1 months; p=0.022; HR 0.67, 95% CI [0.48, 0.95]). At ESMO 2025, ITM announced that the COMPETE trial also met a key secondary endpoint of objective response rate (ORR) (21.9% vs 4.2%, p<0.0001).

In this analysis of the COMPETE trial presented at NANETS 2025, the key findings showed:

- ORR was higher in patients in the ^{177}Lu-edotreotide arm vs. everolimus across subgroups, including those with pancreatic NETs, Grade 1 tumors, Grade 2 tumors, and those who had received prior therapy (2nd line); post-hoc analysis
- Although data is still maturing, there was a preliminary trend of longer median overall survival (OS) in the ^{177}Lu-edotreotide arm vs. everolimus in most patient subgroups

ORR and OS Subgroup Analyses Based on Blinded Independent Central Review (BICR): Phase 3 COMPETE Trial ^{177}Lu-edotreotide (n=207 patients) vs. everolimus (n=102 patients)		
	Objective Response Rate (ORR); post-hoc analysis	**Overall Survival (OS)**
Primary Tumor Origin Gastroenteric NET	6.0 % v. 5.0%	63.4 months v. 58.7 months (p value = 0.799)
Pancreatic NET	33.3% v. 3.6%	65.7 months v. 49.3 months (p value=0.263)
Tumor Grade [1] Grade 1	15.8% v. 3.3%	NR[2] v. NR (p value=0.702)

Grade 2	28.3% v. 3.1%	56.7 months vs. 41.4 months (p value=0.082)
Prior Medical Therapy Treatment-naïve (1st line)	17.9% v. 5.9%	57.4 months v. NR (p value= 0.016)
Prior therapy (2nd line)	22.5% v. 3.8%	63.4 months v. 43.4 months (p value=0.018)
[1]Central assessment according to WHO classification, [2]Not reached		

"We are encouraged by the positive trends we see in PFS extension and higher ORR for ^{177}Lu-edotreotide compared to everolimus in these patient subgroups. These results strengthen the existing data set for Lu-edotreotide's potential as a new therapeutic option for people living with inoperable GEP-NETs," said **Dr. Capdevila, senior medical oncologist at Vall d'Hebron University Hospital, Barcelona**.

ITM also announced real-world clinical and meta-analysis data in patients with a range of neuroendocrine tumors at NANETS.

In early October, ITM presented dosimetry data from the COMPETE trial at the European Association of Nuclear Medicine (EANM) Annual Congress in Barcelona, Spain. The data showed that ^{177}Lu-edotreotide delivered targeted radiation to tumors while minimizing exposure to healthy tissue, supporting its efficacy and safety profile.

"These additional subgroup data reinforce and extend evidence from the COMPETE Phase 3 trial, supporting ^{177}Lu-edotreotide's potential as a promising radiopharmaceutical therapy for neuroendocrine tumors if approved," said **Dr. Andrew Cavey, chief executive officer of ITM**.

Oral Presentation Details
Title: Efficacy of ^{177}Lu-edotreotide vs everolimus in patients with grade 1 or grade 2 GEP-NETs: Phase 3 COMPETE trial (post hoc subgroup analyses)
Date and Time: October 24, 2025, 3:35-4:50 pm Central Time
Session: Part II Featured Abstracts| Access to New Treatments - How can we bring innovative treatments to patients more quickly and effectively?
Presenter: Jaume Capdevila, MD, PhD, senior researcher, department of Medical Oncology, Vall d'Hebron University Hospital & Vall d'Hebron Institute of Oncology

Poster Presentation Details:
Title: Efficacy of ^{177}Lu-edotreotide vs everolimus in patients with grade 1 or grade 2 GEP-NETs: Phase 3 COMPETE trial (post hoc subgroup analyses)
Date and Time: Friday, October 24, 5:15-6:30 pm Central Time
Session: NANETS Poster Tour
Presenter: Dr. Jaume Capdevila, Vall d'Hebron University Hospital, Barcelona.

Title: First-line Treatment with ^{177}Lu-edotreotide ([^{177}Lu]Lu-DOTATOC) in patients with NETs: a Swiss NET Registry Analysis
Date and Time: Friday, October 24, 5:15-6:30 pm Central Time
Session: NANETS Poster Tour
Presenter: Dr. Guillaume Nicolas, University Hospital Basel

Title: Efficacy and safety of ^{177}Lu-edotreotide ([^{177}Lu]Lu-DOTATOC) for the treatment of neuroendocrine tumors (NETs) – a systematic literature review (SLR) and meta-analysis
Date and Time: Friday, October 24, 5:15-6:30 pm Central Time
Session*:* NANETS Poster Tour
Presenter: Dr. Julia G Fricke, University Hospital Basel

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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