ITM Announces Phase 3 COMPETE Data Demonstrating a Statistically Significant Higher Objective Response Rate with n.c.a. ^{177}Lu-edotreotide (ITM-11) vs. Everolimus in Patients with Gastroenteropancreatic Neuroendocrine Tumors at ESMO 2025

- Study data also showed prolonged progression-free survival with ^{177}Lu-edotreotide compared to everolimus across patient subgroups

Berlin, Germany, October 18, 2025 – ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company, today announced a higher objective response rate (ORR) and prolonged median progression-free survival (mPFS) across subgroups in patients treated with non-carrier-added (n.c.a) ^{177}Lu-edotreotide (also known as ITM-11 or ^{177}Lu-edotreotide) compared to everolimus from its Phase 3 COMPETE trial in Grade 1 or Grade 2 somatostatin receptor (SSTR)-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs). Study investigator Jaume Capdevila, MD, PhD, presented the data in an oral presentation at the European Society for Molecular Oncology (ESMO) Congress, held October 17-21, 2025 in Berlin, Germany.

As announced in January and at ENETS in March 2025, the Phase 3 COMPETE trial met its primary endpoint, demonstrating a statistically significant improvement in mPFS ($p<0.022$) in patients treated with investigational radiotherapeutic agent n.c.a. ^{177}Lu-edotreotide compared with everolimus. The mPFS was centrally assessed by a Blinded Independent Central Review (BICR). A total of 309 patients were randomized to either ^{177}Lu-edotreotide (n=207) or everolimus (n=102).

Key findings included:

- ORR, a key secondary endpoint, was significantly higher in the ^{177}Lu-edotreotide arm vs. everolimus
- mPFS, by central assessment, was longer in the ^{177}Lu-edotreotide arm in patient subgroups: gastroenteric NET, pancreatic NET, Grade 1, Grade 2, 1st line, 2nd line
- Frequency of patients who experienced treatment-emergent adverse events (TEAEs) leading to premature study discontinuation was lower in the ^{177}Lu-edotreotide arm

Objective Response Rate		
	^{177}Lu-edotreotide (n=207) vs. Everolimus (n=102)	**P value, Hazard Ratio (HR)/Confidence Interval (CI)**
ORR		
Central assessment	21.9% vs. 4.2%	p<0.0001
Local assessment	30.5% vs. 8.4%	p<0.0001
Median Progression-Free Survival by Patient Subgroup (Central Assessment)[1]		
Primary Tumor Origin		
Gastroenteric NET	23.9 vs. 12.0 months	p=0.090; HR 0.64, 95% CI [0.38, 1.08]
Pancreatic NET	24.5 vs. 14.7 months	p=0.114; HR 0.70, 95% CI [0.45, 1.09]
Tumor Grade[2]		
Grade 1	30 vs. 23.7 months	p=0.753; HR 0.89, 95% CI [0.42, 1.87]
Grade 2	21.7 vs. 9.2 months	p=0.003; HR 0.55, 95% CI [0.37, 0.82]

Prior Medical Therapy Treatment-naïve (1st line) Prior therapy (2nd line)	 NR[3] vs.18.1 months 23.9 vs. 14.1 months	 p=0.249; HR 0.60, 95% CI [0.25, 1.45] p=0.039; HR 0.68, 95% CI [0.47, 0.98]
[1]Unstratified statistics [2]Tumor grade was determined locally, per protocol [3] Not reached		
Premature Study Discontinuations		
Frequency of Trial Discontinuations Related to Treatment-Emergent Adverse Events (TEAEs)	1.8% vs. 15.2%	

"The prolonged PFS observed across patient subgroups reinforces the consistent therapeutic effect and safety profile of ^{177}Lu-edotreotide," said **Dr. Capdevila, senior medical oncologist at Vall d'Hebron University Hospital, Barcelona**. *"Importantly, the low rate of discontinuations due to treatment-emergent adverse events underscores ^{177}Lu-edotreotide's tolerability."*

"These additional results, in particular meeting a key secondary endpoint of objective response rate, reinforce ^{177}Lu-edotreotide's potential as an important treatment option for GEP-NET patients," said **Dr. Andrew Cavey, chief executive officer of ITM**. *"The COMPETE trial demonstrated that many patients experienced partial or complete responses with ^{177}Lu-edotreotide."*

Recently, ITM presented dosimetry data from the COMPETE trial in an oral presentation 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. The presentation by Dr. Emmanuel Deshayes, COMPETE study investigator and nuclear medicine physician, received the Marie Curie Award, in recognition of exceptional scientific quality and contribution to the field of nuclear medicine.

Oral Presentation Information:

Title: "Efficacy, safety and subgroup analysis of ^{177}Lu-edotreotide vs everolimus in patients with Grade 1 or Grade 2 GEP-NETs: Phase 3 COMPETE trial"
Date and Time: October 18, 2025, 11:05-11:15 am CEST, followed by Q&A and discussion
Session and Room Number: NETs and endocrine tumours Proffered Paper session
Karlsruhe Auditorium - Hall 5.2
Presenter: Jaume Capdevila, MD, PhD, study investigator and senior medical oncologist at Vall d'Hebron University Hospital, Barcelona

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 gastroenteropancreaticneuroendocrine 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 GEP-NETS

Neuroendocrine tumors (NETs) are a rare form of cancer, with an estimated 8 new cases per 100,000 individuals diagnosed each year in the U.S. and 9 cases per 100,000 in Europe. The incidence of NETs has steadily increased over recent decades, resulting, in part, from improved diagnosis. Gastroenteropancreatic neuroendocrine tumors (GEP-NETS) originate in the neuroendocrine system and are made up of nerve cells and hormone-producing cells. They can occur anywhere in the GI tract and pancreas, including the stomach, small intestine, colon, rectum, and appendix. There is still a high

unmet medical need for treatment options, as many patients are asymptomatic and diagnosed at a late stage with metastatic disease.

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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