ITM Announces Primary Results from the Phase 3 COMPETE Trial Published in *The Lancet* Comparing ^{177}Lu-edotreotide (ITM-11) vs. Everolimus in Advanced GEP-NETs

- Investigational n.c.a. ^{177}Lu-edotreotide (ITM-11) demonstrated a significantly higher progression-free survival and objective response rate vs. everolimus

Garching / Munich, July 7, 2026 – ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company, today announced the publication of its primary result analysis of the Phase 3 COMPETE trial in *The Lancet*. The clinical data demonstrated that non-carrier-added (n.c.a.) ^{177}Lu-edotreotide (also known as ^{177}Lu-edotreotide or ITM-11) significantly improved progression-free survival (PFS) compared to everolimus in patients with Grade 1 or Grade 2 somatostatin receptor (SSTR)-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs).

The publication, titled "[^{177}Lu] Lu-edotreotide versus everolimus for gastroenteropancreatic neuroendocrine tumours (COMPETE): a phase 3, multicentre, randomised, open-label, superiority trial," appeared online on July 2, 2026, and can be accessed via the following link: doi.org/10.1016/S0140-6736(26)00604-5.

"COMPETE provides the first high-level evidence directly comparing peptide receptor radionuclide therapy (PRRT) with everolimus, a commonly used systemic standard-of-care therapy, in the treatment of advanced GEP-NETs," said **Jaume Capdevila, MD, PhD, last author, study investigator and senior medical oncologist at Vall d'Hebron University Hospital, Barcelona**. "The efficacy and safety results observed with ^{177}Lu-edotreotide support its consideration as a potential treatment option for appropriate patients, including those whose disease has progressed following somatostatin analog (SSA) therapy."

"Publication of these data in a peer-reviewed journal underscores the scientific importance of the COMPETE study and provides an important forum for dissemination of the results," added **Thomas Walter, MD, PhD, first author, study investigator and professor of gastroenterology, Hospices Civil of Lyon, France**. "These findings offer additional insights into PRRT and support ^{177}Lu-edotreotide as a potential therapeutic option in advanced GEP-NETs, where a high unmet need remains."

COMPETE Trial Results

The randomized, open-label Phase 3 COMPETE trial evaluated n.c.a. ^{177}Lu-edotreotide versus everolimus in 309 patients with advanced, progressive, Grade 1 or Grade 2 SSTR-positive GEP-NETs across 49 global sites. Patients were randomized 2:1 to receive ^{177}Lu-edotreotide every three months for up to four cycles or everolimus daily for up to 30 months. Patients were not required but permitted to receive SSAs at the investigator's discretion for symptom control only. Overall, 21% of patients

received concomitant SSA treatment during the study, with similar proportions receiving SSAs in each treatment arm. Top line results of the trial were initially presented at ENETS 2025 and ESMO 2025.

Key findings from the COMPETE trial include:

- Median PFS was significantly longer in the ^{177}Lu-edotreotide arm compared to everolimus (23.9 vs. 14.1 months; p=0.022; HR 0.67, 95% CI [0.48–0.95])
- Objective response rate (ORR) was significantly higher in the ^{177}Lu-edotreotide arm compared to everolimus in central review (22% vs. 4%; p<0.0001)
- Safety data demonstrated a lower incidence of Grade 3/4 treatment-related adverse events in patients receiving ^{177}Lu-edotreotide compared to everolimus (18% vs. 40%)
- The most common treatment-related adverse events in the ^{177}Lu-edotreotide arm were diarrhea and nausea (both 36%) and asthenia (33%), whereas those in the everolimus arm were diarrhea (45%), asthenia (36%), and anemia (27%)

Notably, a substantial proportion of patients enrolled in COMPETE had pancreatic neuroendocrine tumors (n=178, 57.6%), where treatment options remain limited. ITM will continue to monitor patients for up to five years after the end of the study to gather additional safety and overall survival data.

"The COMPETE results add to the evidence base of PRRT in advanced GEP-NETs and help address an important evidence gap, given the limited prospective, head-to-head trials versus active therapies in this setting," said **Dr. Celine Wilke, chief medical officer of ITM.** "These data support the potential role of investigational ^{177}Lu-edotreotide as a treatment option in this indication, if approved."

ITM-11 is currently under regulatory review by the U.S. Food and Drug Administration and is not approved by any regulatory authority for any use.

About GEP-NETs

Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) are a heterogeneous group of rare tumors arising from neuroendocrine cells in the gastrointestinal tract and pancreas. Many patients present with advanced disease, and treatment options are often limited following progression on first-line therapies.

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 standard-of-care 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

(NCT04919226), a Phase 3 study in patients with well-differentiated, aggressive Grade 2 or Grade 3, SSTR-positive GEP-NET tumors, and in KinLET (NCT06441331), a Phase 1 trial in pediatric patients with SSTR-positive 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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