

ITM Announces Phase 3 COMPETE Trial Post-Hoc Subgroup Analyses with n.c.a. ¹⁷⁷Lu-edotreotide (ITM-11) in Patients with Pancreatic Neuroendocrine Tumors at ENETS 2026 Conference

- Median progression-free survival (PFS) in pancreatic neuroendocrine tumor (P-NET) patients was 24.5 months on ¹⁷⁷Lu-edotreotide arm vs. 14.7 months on everolimus arm
- Objective response rate (ORR) was higher across the majority of P-NETs subgroups

Krakow, Poland, March 5, 2026 – [ITM Isotope Technologies Munich SE \(ITM\)](#), a leading radiopharmaceutical biotech company, today presented post-hoc subgroup analyses of the ITM-11 Phase 3 COMPETE trial in patients with Grade 1 or Grade 2 somatostatin receptor (SSTR)-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs). In patients with pancreatic neuroendocrine tumors (P-NETs), data showed that n.c.a. ¹⁷⁷Lu-edotreotide (ITM-11) prolonged progression-free survival (PFS) and achieved higher objective response rates (ORR) when compared to everolimus. Data were presented by Thomas Walter, MD, PhD, professor of gastroenterology, Hospices Civils de Lyon, France, in a mini-oral presentation and in an accompanying poster at the 23rd Annual Meeting of the European Neuroendocrine Tumor Society (ENETS), held March 4-6, 2026 in Krakow, Poland.

As previously announced at [ENETS 2025](#), the COMPETE trial met its primary endpoint of 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 COMPETE also met a key secondary endpoint of ORR (21.9% vs 4.2%, p<0.0001) in patients with GEP-NETs.

The COMPETE study enrolled a total of 309 GEP-NET patients, including 178 (57.6%) patients with P-NETs randomized 2:1 to either ¹⁷⁷Lu-edotreotide (n=119) or everolimus (n=59). Of the 178 P-NET patients, 150 (84.3%) had non-functional tumors, meaning they did not produce hormones causing clinical symptoms, and 28 (15.7%) had functional tumors, in which excess hormone production can cause symptoms such as hypoglycemia (insulinoma), or diarrhea and peptic ulcer (Zollinger Ellison syndrome).

Key findings in the P-NETs population showed:

- Median PFS was longer in the ¹⁷⁷Lu-edotreotide arm compared to everolimus (24.5 months vs. 14.7 months; p=0.114; HR 0.70, 95% CI [0.45, 1.09]) and ORR in the ¹⁷⁷Lu-edotreotide arm was 33.3% vs. 3.6% in everolimus arm.
- ORR in the ¹⁷⁷Lu-edotreotide arm was ≥ 30% in P-NET patients with non-functional disease, across all patients regardless of line of therapy and Ki-67 index. This includes 38.1% ORR in P-NET patients with non-functional disease and 34.2% ORR in patients with a Ki-67 index ≥10%.

- Median overall survival was numerically longer in the ¹⁷⁷Lu-edotreotide arm compared to everolimus (65.7 months vs. 49.3 months) at the time of analyses; data continue to mature with ongoing five-year follow up.
- The overall safety profile in P-NET patients receiving ¹⁷⁷Lu-edotreotide compared to everolimus was similar or potentially improved, and included fewer serious adverse events (SAEs) (29.1% vs. 43.1%). Lower incidence of adverse events suspected to be related to the study drug was seen in the ¹⁷⁷Lu-edotreotide arm vs. everolimus arm (83.8% vs. 96.6%).

“Given that the data on peptide receptor radionuclide therapy in pancreatic NETs has been limited to date, we are encouraged by the activity of ¹⁷⁷Lu-edotreotide observed in this prespecified exploratory subgroup of patients with Grade 1 or 2 pancreatic NETs, who represented approximately 58% of trial participants,” said **Thomas Walter, MD, PhD, professor of gastroenterology, Hospices Civil of Lyon, France.**

“These additional results from our Phase 3 COMPETE trial provide important insights into treatment options for patients with pancreatic NETs, and further enhance the robust clinical data of ¹⁷⁷Lu-edotreotide,” said **Dr. Celine Wilke, chief medical officer of ITM.**

¹⁷⁷Lu-edotreotide (ITM-11) is an investigational product pending review by the U.S. Food and Drug Administration (FDA) and is not approved by any regulatory authority for the safety and/or efficacy of any intended use.

ENETS Oral Presentation Details

Title: ¹⁷⁷Lu-edotreotide for the Treatment of Pancreatic Neuroendocrine Tumours: A Subgroup Analysis from the COMPETE Study

Date and Time: March 5, 2026, 11:00 am-12:30 pm CET Session; 11:50-11:57 am CET Oral Presentation

Session and Room Number: Clinical Science, Session 2B: Abstract session; Theatre Hall (S2)

Presenter: Thomas Walter, PhD, MD, Professor of Gastroenterology, Hospices Civil of Lyon, France

The e-poster will be accessible to registered participants during the event and available on www.enets.org after the conference.

About the COMPETE Trial

The COMPETE trial (NCT03049189) evaluated ¹⁷⁷Lu-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 ¹⁷⁷Lu-edotreotide demonstrating clinically and statistically significant improvement in progression-free survival (PFS) compared to everolimus. ¹⁷⁷Lu-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

ITM Contacts:

Corporate Communications

Kathleen Noonan/Julia Westermeir

Phone: +49 89 329 8986 1500

Email: communications@itm-radiopharma.com

Investor Relations

Ben Orzelek

Phone: +49 89 329 8986 1009

Email: investors@itm-radiopharma.com