ITM Announces Phase 3 COMPETE Data Supporting Single-Timepoint Dosimetry for n.c.a. ^{177}Lu-edotreotide (ITM-11) in Patients with Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) at SNMMI 2026

- Analysis from the Phase 3 COMPETE trial suggests population-based modeling may enable accurate individualized dosimetry with substantially fewer imaging requirements

Los Angeles, California, June 1, 2026 — ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company, today announced new single-timepoint dosimetry data from its Phase 3 COMPETE trial in patients with gastroenteropancreatic neuroendocrine tumors (GEP-NETs). The data were presented in a poster presentation at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting, held from May 30 – June 2, 2026, in Los Angeles, CA.

As previously reported at ENETS 2025, the Phase 3 COMPETE trial met its primary endpoint, with ^{177}Lu-edotreotide (ITM-11) demonstrating clinically and statistically significant improvement in progression-free survival compared to everolimus (23.9 vs. 14.1 months; p=0.022). Results from a prospective dosimetry sub-study of COMPETE were presented at EANM 2025. Data, which included one of the largest prospective dosimetry datasets ever generated in a Phase 3 radiopharmaceutical trial, demonstrated that ^{177}Lu-edotreotide (ITM-11) delivered targeted radiation to tumors while maintaining healthy organ exposure well below established safety thresholds. Building on this dataset, investigators applied PBMS NLMEM modeling to evaluate whether accurate individualized dose estimates for kidneys and tumors could be achieved from a single imaging session.

“Individualized dosimetry has long been recognized as clinically valuable in radiopharmaceutical therapy, but widespread implementation has been limited by the complexity and burden of repeated imaging procedures,” said **Dr. Deni Hardiansyah, co-author and associate professor at the University of Indonesia**. “These findings demonstrate that a population-based modeling approach may enable accurate dosimetry estimates using substantially fewer imaging timepoints, supporting more practical integration into routine clinical practice.”

The analysis utilized dosimetry data from patients treated with ^{177}Lu-edotreotide in the Phase 3 COMPETE trial, including planar and SPECT/CT imaging data collected from 207 kidney datasets and 154 tumor datasets. Investigators evaluated the accuracy of PBMS NLMEM-derived single-timepoint dosimetry estimates compared with established Madsen and Hänscheid approaches.

Key findings included:

- The PBMS NLMEM approach accurately estimated absorbed doses for both kidneys and tumors using a single imaging timepoint, achieving mean absolute percentage error (MAPE) values of 3–20% for kidney dosimetry across evaluated timepoints
- PBMS NLMEM outperformed comparator single-timepoint dosimetry methods with respect to MAPE and R20 for kidney absorbed dose estimation across all evaluated timepoints

- Findings suggest individualized dosimetry may be achievable with just one scan approximately six hours after treatment, offering an alternative for centers with limited imaging capacity and potentially expanding the routine use of personalized dosimetry

"These data build on the extensive dosimetry dataset generated through the COMPETE trial and reflect ITM's continued commitment to advancing precision radiopharmaceutical therapy," said **Dr. Celine Wilke, chief medical officer of ITM**. "The possibility of accurate, same-day dosimetry from a single scan may help reduce patient burden and workflow complexity, as well as reduce inter-center disparities, making personalized dosimetry practical for a far broader range of clinical settings."

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 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. It is also being evaluated in COMPOSE, a Phase 3 study in patients with well-differentiated, aggressive Grade 2 or Grade 3, somatostatin receptor (SSTR)-positive GEP-NETs.

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. ITM aims to meet the needs of cancer patients, clinicians and partners through excellence in development, production and global supply of medical radioisotopes. With improved patient benefit as the driving principle, 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 two decades of pioneering radiopharma expertise, a central industry position and an 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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