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177Lu-edotreotide Improves PFS in Grade 1/2 GEP-NETs in Phase 3 COMPETE Trial

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Key Takeaways

- 177Lu-edotreotide improved progression-free survival over everolimus in grade 1 or 2 GEP-NETs, meeting the primary endpoint of the COMPETE trial.
- The therapy demonstrated favorable safety and tolerability, with plans for further FDA discussions and potential new drug application submission in 2025.

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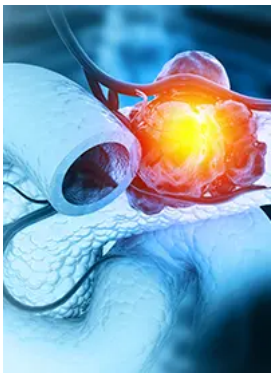
177Lu-edotreotide prolonged PFS vs everolimus in patients with inoperable, progressive, grade 1 or 2 gastroenteropancreatic neuroendocrine tumors.



Pancreatic Cancer | Image Credit: © Crystal light - stock.adobe.com

The proprietary, synthetic, targeted radiotherapeutic agent 177 Lutetium edotreotide (ITM-11; ^{177}Lu-edotreotide) extended progression-free survival (PFS) vs everolimus (Afinitor) in patients with inoperable, progressive, grade 1 or 2 gastroenteropancreatic neuroendocrine tumors (GEP-NETs), meeting the primary end point of the phase 3 COMPETE trial (NCT03049189).[1]

The treatment was also well tolerated with favorable safety data according to the drug's developer, ITM, who intends to submit the findings for presentation at an upcoming medical meeting. The company also expects to discuss a pathway toward a new drug application submission with the FDA in 2025.

"With COMPETE, this marks the first time that a targeted radiopharmaceutical therapy has demonstrated improved progression-free survival compared to a targeted molecular therapy, everolimus, in patients with grade 1 and grade 2 GEP-NET tumors in a phase 3 clinical trial. The patients included represent a real-life scenario, and the COMPETE study evaluates the important question of which therapy might be used first to provide greater benefit to patients," Jaume Capdevila, MD, PhD, study investigator and senior medical oncologist at Vall d'Hebron University Hospital, Barcelona, stated in a news release. "As a clinician, I am highly encouraged by these data and look forward to seeing further results."

^{177}Lu-edotreotide is a radiolabeled peptide conjugate that releases β radiation to SSTR-positive tumor cells via intravenous administration, sparing healthy organs and tissue. ^{177}Lu-edotreotide is made up of non-carrier-added lutetium-177, a therapeutic β-emitting radioisotope, and edotreotide, a synthetic somatostatin receptor (SSTR) agonist.

In 2022, the **FDA granted fast track designation to ^{177}Lu-edotreotide** for the treatment of patients with GEP-NETs based in part on data from the COMPETE trial.[2]

COMPETE is a prospective, randomized, controlled, open-label phase 3 trial evaluating the efficacy and safety of ^{177}Lu-edotreotide vs standard-of-care (SOC) treatment with everolimus.[1] The trial enrolled 309 patients with grade 1 or grade 2 inoperable, progressive, SSTR-positive NETs of gastroenteric or pancreatic origin with a Ki-67 index of 20% or less.

Patients were randomly assigned 2:1 to receive 7.5 GBq of ^{177}Lu-edotreotide with a nephroprotective amino acid solution every 3 months for up to 4 cycles, or 10 mg of everolimus daily for up to 30 months, or until disease progression.

The trial's secondary end points include objective response rate, overall survival, and quality of life assessments. Notably, dosimetry was used to evaluate the dose of ^{177}Lu-edotreotide that was absorbed in tumors vs that in healthy tissue to augment safety and efficacy assessments. Evaluation of the dosimetry data, secondary end points, and supplementary subgroup analyses are underway.

In addition to the COMPETE trial, ^{177}Lu-edotreotide is being studied in the phase 3 COMPOSE trial (NCT04919226) in

patients with well-differentiated, aggressive grade 2 or grade 3, SSTR-positive GEP-NETs. The prospective, randomized, controlled, open-label trial is comparing the efficacy, safety, and patient-reported outcomes of ^{177}Lu-edotreotide as first- or second-line treatment with physician's choice of SOC chemotherapy.

Additionally, ^{177}Lu-edotreotide is being tested in the phase 1 KinLET trial (NCT06441331) in pediatric patients with SSTR-positive tumors and the phase 3 investigator-sponsored LEVEL trial (NCT05918302) in patients with lung and thymus NETs.

"We want to thank the patients, families and caregivers, and investigators for their commitment to and trust in this trial. People with GEP-NETs, whose journey from diagnosis to proper treatment can take years, remain in significant need of more robust, data-driven treatment options to maximize outcomes. The successful COMPETE data support ITM-11's potential and we believe mark an important milestone for patients and for ITM," Andrew Cavey, MD, chief executive officer of ITM, added in the news release. "Our organization now has demonstrated both early and late-stage clinical development capabilities that complement our leadership in global isotope manufacturing."

References

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2. 2.ITM receives FDA fast track designation for radionuclide therapy candidate ITM-11 (n.c.a. ^{177}Lu-edotreotide) in neuroendocrine tumors (GEP-NETs). News release. ITM Isotope Technologies Munich SE. October 27, 2022. Accessed January 28, 2025. https://www.itm-radiopharma.com/news/press-releases/press-releases-detail/itm-receives-fda-fast-track-designation-for-radionuclide-therapy-candidate-itm-11-nca-177lu-edotreotide-in-neuroendocrine-tumors-gep-nets-1-592/