



NUCLIDIUM Presents Positive Phase I/II Results for First Copper-based PET Diagnostic in Neuroendocrine Tumors at EANM Congress 2025

- ^{61}Cu -TraceNET™ showed an excellent safety profile and was well tolerated with rapid blood clearance and a favorable half-life enabling broader biodistribution and extending time points for imaging
- Dosimetry data demonstrated increased tumor uptake and improved tumor-to-background ratio for ^{61}Cu -TraceNET™ compared to standard of care with additional metastases detected in the liver and lungs
- Positive proof-of-concept results provide strong basis to advance the diagnostic and corresponding therapeutic into clinical trials for SSTR2-positive metastatic breast cancer in 2026

Basel, Switzerland, October 08, 2025 – [NUCLIDIUM AG](#), a clinical-stage radiopharmaceutical company developing a proprietary copper-based theranostic platform, today announced positive clinical data from the ongoing Phase I/II trial ([NCT06455358](#)) evaluating its novel copper-radiolabeled PET tracer, ^{61}Cu -TraceNet™ (^{61}Cu]-Cu-NODAGA-LM3) in patients with SSTR-positive gastroenteropancreatic and bronchopulmonary neuroendocrine tumors (GEP & BP-NETS). Principal investigator Dr. Guillaume Nicolas, Deputy Head of Nuclear Medicine at the Department of Theragnostics at University Hospital Basel, Switzerland, presented the results in an oral session during the European Association of Nuclear Medicine (EANM) Congress in Barcelona, Spain.

The first-in-human, open-label, randomized, reader-blinded, Phase I/II study compared the safety, biodistribution, tumor uptake, and image quality of NUCLIDIUM's copper-61-radiolabeled somatostatin receptor subtype 2 (SSTR2) antagonist, ^{61}Cu -TraceNet™ with the standard of care gallium-68-labelled SSTR2 agonist, [^{68}Ga]-Ga-DOTA-TOC. In the first 22 patients with well-differentiated GEP and BP-NETS evaluated at the University Hospital Basel, ^{61}Cu -TraceNET™ was well tolerated with no clinically significant adverse events reported. ^{61}Cu -TraceNET™ showed a higher tumor uptake and tumor-to-background ratio and detected additional lesions in the liver and lungs. In a blinded analysis, independent readers rated the ^{61}Cu -TraceNET™ image quality as superior compared to ^{68}Ga -DOTATOC at both 1- and 3-hour imaging post-injection, supported by its 5.6-hour half-life, which enables broader distribution and delayed imaging. The image quality of ^{61}Cu -TraceNET at 1- and 3-hours post-injection was assessed as equally good.

"Next-generation radiopharmaceuticals have the potential to transform the diagnosis and management of difficult-to-treat cancers. The first-in-human data with NUCLIDIUM's novel copper-based diagnostic, ^{61}Cu -TraceNET™, show its excellent tumor specificity, improved image quality, and its ability to detect additional metastases," said **Guillaume Nicolas, MD, PhD, Principal Investigator of the trial**. "I am also encouraged by the safety, pharmacokinetic data, and the strong potential for ^{61}Cu -TraceNET™ to support clinicians in the diagnosis in a range of SSTR2-positive tumors, including metastatic breast cancer, where better diagnostic approaches are urgently needed to improve treatment strategies."

Leila Jaafar, PhD, CEO and Co-Founder of NUCLIDIUM added, "This rapidly generated first clinical data with ^{61}Cu -TraceNET™ validates the potential of our copper-based platform and our ability to radiolabel an SSTR2 antagonist with high yield at room temperature for convenient patient diagnosis. With high specificity, low toxicity, and the potential to detect even the smallest primary and metastatic tumors early, ^{61}Cu -TraceNET is well positioned to become a best-in-class diagnostic. We remain committed to rapidly advancing our copper-based theranostic pipeline to improve outcomes for patients across multiple cancer types with a focus on women's health."

^{61}Cu -TraceNET™ is the diagnostic component of NUCLIDIUM's TraceNET™ program, targeting NETs and other SSTR-positive tumors such as metastatic breast cancer. A clinical trial of the corresponding therapeutic, ^{67}Cu -TraceNET™, is expected to start enrolling patients in 2026.

About NUCLIDIUM

NUCLIDIUM AG is a clinical-stage biotechnology company pioneering the development of next-generation copper-based radiopharmaceuticals for the diagnosis and treatment of cancer. Leveraging copper isotopes



– Copper-61 for diagnostics and Copper-67 for therapeutics – NUCLIDIUM is creating a differentiated platform with the potential to overcome existing limitations in radiotheranostics. The company's operations in Switzerland and Germany combine innovative chemistry, deep clinical expertise, and strategic manufacturing capabilities to deliver scalable, accessible, and clinically superior theranostic solutions to patients worldwide. NUCLIDIUM is committed to expanding the reach and efficacy of radiotheranostics, including addressing critical unmet medical needs in oncology and women's health.

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