

NUCLIDIUM and University Hospital Basel Receive NETRF Investigator Award to Initiate Phase 1 Trial with Novel Copper-based Radiotheranostic Program TraceNET™ in Neuroendocrine Tumours

Basel, Switzerland, March 21, 2023 – [NUCLIDIUM](#) today announced that the [Neuroendocrine Tumors Research Foundation](#) (“NETRF”) has selected the company and its collaboration partner the [University Hospital Basel](#) (Universitätsspital Basel, “USB”) as recipients of its Investigator Award. The grant will support the initiation and execution of a Phase 1 clinical trial with TraceNET™, a novel copper-based radiodiagnostic for detecting neuroendocrine tumours (NET). The PET imaging agent candidate is the diagnostic component of NUCLIDIUM’s theranostic program, which comprises a true theranostic pair for diagnosing and treating NET patients, leveraging the company’s unique copper-based approach. The Phase 1 program for the diagnostic is the first step in its clinical development and is planned to commence in the first half of 2023.

Nuclidium’s TraceNET™ program aims to overcome key limitations of existing radiodiagnostics and their corresponding therapeutics by increasing the sensitivity and diagnostic accuracy of NET imaging, including detecting metastases, while reducing the radiation burden for the patient. The TraceNET™ diagnostic consists of an imaging radioisotope (^{61}Cu) and a somatostatin receptor (SSTR) antagonist-targeting molecule that binds with high affinity and specificity to SSTRs overexpressed on the surface of NET cells.

NETs are a rare cancer indication originating in neuroendocrine cells located mainly in the gastrointestinal tract and the pancreas. Often asymptomatic and difficult to detect, they are usually only diagnosed at an advanced or metastatic stage associated with significantly reduced survival rates. In addition, up to 50% of NET patients are wrongly staged, preventing them from receiving the right treatment. Currently, available therapeutics for advanced NET, including chemotherapy and targeted radiotherapy, are still facing challenges like toxic side effects, limited efficacy and availability.

NUCLIDIUM and the USB will combine their know-how and resources for this first-in-human study with TraceNET™ on their joint mission to provide NET patients with a new diagnostic that offers improved precision, performance, and accessibility. The Phase 1 study will assess the safety, biodistribution, pharmacokinetics and dosimetry of TraceNET™ in NET patients. It will also analyse the performance of TraceNET™ in positron emission tomography (PET)/computed tomography (CT) imaging compared to ^{68}Ga -DOTATOC, the current state-of-the-art imaging agent for the detection of NET in the same patients.

“The Investigator Award underlines the unique potential of our copper-based theranostic approach that, for the first time, allows the development of a true theranostic, leveraging the same radiometal and targeting molecule. There is a persistent need for better theranostics to ensure the best possible care for NET patients at all stages of their disease. Together with the USB, our vision is to set a new standard in precision oncology by enabling easy access to highly effective and safe diagnostics and treatment options for cancer patients. We are looking forward to rapidly advancing our first program TraceNET™ into a first-in-human trial only 1,5 years after we initiated its development,” said **Leila Jaafar, PhD, CEO and Co-Founder of NUCLIDIUM**.

“Despite the advancements in the field, NETs still have a low survival rate of less than 30% at advanced stages, highlighting the urgent demand for seamlessly transferrable theranostic treatment concepts. This award enables us to translate our distinct scientific concept into clinical application, which is an important step on our way to creating improved radiopharmaceuticals for cancer indications with a high medical need,” added **Prof. Melpomeni Fani, PhD, PI of the Phase 1 trial and Division Head Radiopharmaceutical Chemistry at USB**.

Nuclidium’s copper-based platform enables an easy adjustment of each product candidate from a diagnostic to a therapeutic by simply exchanging ^{61}Cu with ^{67}Cu . Through this approach, both product candidates are biodistributed in the body identically, allowing for exact dosimetry for each patient. This seamless “diagnostic to therapeutic” approach offers the potential for more personalised, efficacious, and safe NET patient care compared to other radiopharmaceuticals that use different radioisotopes and/or targeting molecules for diagnosis and treatment. Importantly, the easy-to-apply proprietary production process and half-live properties of the copper radioisotopes contribute to a superior radiotheranostic product with broad availability.



The NETRF's Investigator Award aims to support innovative and transformative research projects to help bring the NET field closer to more effective therapies. It encourages multidisciplinary groups comprised of basic scientists, clinicians and experts across relevant cutting-edge areas to jointly apply their know-how to developing novel ideas and strategies to improve the lives of NET patients. The Investigator Award is granted to one or two applicants each year and supports projects for two years.

About Neuroendocrine Tumours

Neuroendocrine tumours (NETs) are a rare form of cancer that develops in cells of the neuroendocrine system. Spread throughout the body, neuroendocrine cells can receive neuronal input like nerve cells (neurons) and produce and release hormones like cells of the endocrine system (endocrine cells). They are mainly found scattered in the gastrointestinal tract (including the small intestine, rectum, stomach, colon, oesophagus, and appendix), the gallbladder, the pancreas (islet cells) and the thyroid (C cells). NETs are difficult to detect and are usually found at an advanced stage. Like prostate cancer, the survival rate significantly drops the more advanced or metastasised the tumour is (5-year survival for metastatic pancreatic NETs: 24 %).

About TraceNET™

Our TraceNET™ program targets somatostatin type II receptors, a clinically validated NET cell marker. Our ⁶¹Cu-based TraceNET™ diagnostic component is highly precise and enables a technique called delayed imaging, where even the smallest tumours can be detected early. Based on these imaging data, our ⁶⁷Cu-based TraceNET™ therapeutic can enable targeted treatment with an improved safety and efficacy profile and reduced radiation burden for the patient.

About NUCLIDIUM

NUCLIDIUM is setting a new standard in the precision oncology landscape by developing best-in-class copper-based radiopharmaceuticals that enable the highest accuracy and accessibility for targeted cancer treatment and diagnosis. Our flexible CuTrace™ platform combines copper radiometals with a variety of highly specific cancer-targeting molecules to rapidly develop novel diagnostic and therapeutic programs. The resulting product portfolio leverages the unique properties of copper to achieve an improved safety and efficacy profile with advantageous economics for hospitals and patients. NUCLIDIUM's differentiated "diagnostic to therapeutic" approach de-risks our development pathway. With innovation as our core, we overcome supply limitations in manufacturing and distribution, bringing greater flexibility to medical facilities. We are a diverse and interdisciplinary team focused on changing precision radio-oncology for the better to deliver a true benefit to cancer patients.

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