

## **NUCLIDIUM to Present Data from Three Clinical-Ready Precision Oncology Programs at the 36<sup>th</sup> Annual EANM Congress**

Basel, Switzerland, September 05, 2023 – [NUCLIDIUM](#) today announced the presentation of pre-clinical and clinical translation data from three of the company's precision oncology programs targeting epithelial tumours (Kalios™), neuroendocrine tumours (TraceNET™) and prostate cancer (NuriPro™) at the upcoming 36<sup>th</sup> Annual Congress of the European Association of Nuclear Medicine (EANM), 09-13 September 2023. The full pre-clinical data packages demonstrate the company's progress in the selection of diagnostic lead candidates for the Kalios™ and NuriPro™ programs, as well as the successful establishment of a clinical-scale production process for the diagnostic component of its TraceNET™ program. The data, presented in two oral presentations and a poster presentation, support the advancement of these three programs into clinical translation. The programs are part of NUCLIDIUM's comprehensive pipeline of copper-based radiotheranostics based on its flexible CuTrace™ platform.

"More than 50% of cancer patients are misdiagnosed which significantly impacts their survival chances. We aim to address this challenge with our theranostic approach leveraging the advantageous properties of copper isotopes to reduce side effects and increase the precision and efficacy of radiopharmaceuticals. The positive pre-clinical data for the diagnostic candidates from three of our programs and the preparation for clinical translation represent an important step for NUCLIDIUM. Our rapid progress towards clinical evaluation will help us establish a new standard in precision oncology and offer patients better access to highly effective and safe diagnostics and treatment options," said **Leila Jaafar, PhD, CEO and Co-Founder of NUCLIDIUM**.

### **Presentation Information:**

*Oral presentation on the development of diagnostic candidates from the Kalios™ program targeting Fibroblast Activation Protein (FAP)-expressing tumours such as breast and lung cancer*

**Title:** Enhancing the tumor-to-background ratio of FAP-positive PET/CT scans with the novel <sup>61</sup>Cu-Kalios derivatives: synthesis, *in vitro* and *in vivo* characterization

**Session:** New Roads Towards FAP-directed Theranostics

**Presenter:** Jacopo Millul, PhD, Postdoctoral Scientist at University Hospital Basel

**Date & Time:** September 11<sup>th</sup>, 3 pm CEST

### **Summary:**

The presentation will detail the development and characterization of a <sup>61</sup>Cu-based diagnostic to more efficiently visualize epithelial tumours. These types of tumours make up the majority of all cancer cases and often overexpress *Fibroblast Activation Protein (FAP)*, making FAP a promising target for cancer diagnostics and therapies. The data demonstrate the successful synthesis of four new FAP-targeting ligands with high hydrophilicity and affinity against FAP that were conjugated with <sup>61</sup>Cu via the NODAGA chelator. *In vivo* analyses showed that two of the diagnostic Kalios™ conjugates are particularly promising for delayed time-point imaging, with superior tumour-to-background ratios at 4 hours. To select the best candidate for clinical translation, these two diagnostic Kalios™ conjugates will be directly compared to a <sup>68</sup>Ga-based standard FAP-radiodiagnostic.

*Oral presentation on NUCLIDIUM's successfully established <sup>61</sup>Cu production and on the labelling method for the diagnostic lead candidate from the TraceNET™ program targeting somatostatin-receptor-expressing neuroendocrine tumours (NETs)*

**Title:** Radiopharmaceutical Production of [<sup>61</sup>Cu]Cu-NODAGA-LM3 Injection Solution

**Session:** Efficient Radiolabelling: Key for Clinical Translation



**Presenter:** Manuel Alejandro-Lafont, PhD, Head QC/QA Radiopharmaceutical Chemistry at University Hospital Basel

**Date & Time:** September 11<sup>th</sup>, 4:45 pm CEST

**Summary:**

The presentation will highlight NUCLIDIUM's <sup>61</sup>Cu production process, which was developed together with the University Hospital Zurich, and the labelling method and clinical transfer for the TraceNET™ lead diagnostic candidate, which was developed at the University Hospital Basel. TraceNET™ is designed to improve the visualization of somatostatin-receptor-expressing neuroendocrine tumours (NETs). The established technology allows to produce <sup>61</sup>Cu in high yields and purity in a cyclotron and efficient labelling of the tumour-targeting molecule. Due to its favourable half-life properties, <sup>61</sup>Cu enables a wide distribution radius, potentially broadening the patient population that can get access to <sup>61</sup>Cu-based radiodiagnostics. The successfully established process enables clinical-scale production of the diagnostic candidate.

*Poster presentation on the development and selection of the lead diagnostic candidate from the NuriPro™ prostate cancer program*

**Title:** <sup>61</sup>Cu-PSMA PET in prostate cancer: development and selection of the first radioligand for clinical translation

**Session:** New Imaging Agents

**Presenter:** Prof. Melpomeni Fani, PhD, Division Head Radiopharmaceutical Chemistry at University Hospital Basel

**Date & Time:** September 13<sup>th</sup>, 9:45 am CEST

**Summary:**

The poster presentation will describe the development and lead candidate selection of the NuriPro™ program's <sup>61</sup>Cu-based diagnostic to improve the visualization of prostate cancer. Two newly developed <sup>61</sup>Cu-based diagnostic conjugates targeting *Prostate-Specific Membrane Antigen* (PSMA) with either DOTAGA or NODAGA as the chelator were compared preclinically against two currently used standard prostate cancer diagnostics based on <sup>68</sup>Ga and <sup>18</sup>F, respectively. In these, the NODAGA-conjugated NuriPro™ diagnostic candidate exhibited superior biodistribution and pharmacokinetics than the DOTAGA-conjugate. In comparison to the standard diagnostics, the NODAGA-conjugated candidate showed a similar biodistribution but better results for delayed imaging due to improved tumour-to-background ratio in the imaging scan. Based on these findings, the NODAGA-conjugated variant was selected as the lead diagnostic candidate for translation into clinical trials.

**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.

**For more information, please contact:**

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