NUCLIDIUM Announces First Patient Imaged in Phase 1 Study Evaluating ^{61}Cu-based Radiotracer in Patients with PSMA-positive Prostate Cancer

Basel, Switzerland, 21 October 2024 – NUCLIDIUM today announced that the first patient has been successfully imaged in a phase 1 clinical trial evaluating the company's radiotracer candidate as a safe and accurate diagnostic and disease-staging imaging agent in prostate cancer patients. ^{61}Cu-NuriPro™ (^{61}Cu-NODAGA-PSMA I&T) is the diagnostic component of NUCLIDIUM's NuriPro™ program, binding specifically to Prostate Specific Membrane Antigen (PSMA). PSMA has evolved as an established biomarker for the diagnosis, staging, and treatment of patients suffering from certain types of prostate cancer.[1,2,3,4] ^{61}Cu-NuriPro is the first candidate from the company's innovative copper-based radiopharmaceutical pipeline to enter the clinic. Its theranostic counterpart, ^{67}Cu-NuriPro™ (^{67}Cu-NODAGA-PSMA I&T), for the treatment of patients with certain types of prostate cancer, is currently completing its preclinical program. A phase 1 clinical study is planned to start in 2025.

The investigator-initiated, non-randomized phase 1 trial is being conducted at Hoag Memorial Hospital Presbyterian in Newport Beach, California. It will evaluate the safety and effectiveness of the NuriPro™ diagnostic candidate for imaging prostate cancer, compared to an ^{18}F-based, FDA-approved PSMA-targeting radiotracer. The ^{61}Cu-based candidate can potentially provide key benefits compared to other established radiotracers. With a 3.3-hour half-life, compared to the 1-to-2-hour half-life of most molecular imaging agents, it allows for a far greater distribution range following production. The company's candidate can be easily manufactured at room temperature, enabling on-demand preparation and a simplified and easy-to-apply workflow with reduced need for laboratory equipment. It further enables delayed imaging, allowing for the detection of even the smallest metastases. Upon successful completion of the trial, NUCLIDIUM will advance the NuriPro™ program into a Phase 1/2 theranostic clinical trial, evaluating both the ^{61}Cu-based imaging agent alongside the ^{67}Cu-based therapeutic candidate.

^{61}Cu-NuriPro can be easily manufactured at room temperature, enabling on-demand preparation and a simplified as well as easy-to-apply workflow with reduced need for laboratory equipment. The diagnostic tracers are manufactured by PharmaLogic Holdings in Los Angeles, CA, and delivered to Hoag in a ready-to-inject form. NUCLIDIUM and PharmaLogic entered into a collaboration agreement in 2023, under which NUCLIDIUM provides PharmaLogic with scientific know-how, proprietary technology, and raw material enabling PharmaLogic to safely and accurately produce high-quality ^{61}Cu-radionuclides and radiopharmaceuticals.

Gary Ulaner, MD, PhD, Director of Molecular Imaging and Therapy at Hoag Memorial Hospital Presbyterian and Principal Investigator of the trial added: "Prostate cancer remains the most frequently diagnosed cancer and the second most common cause of cancer death in American men.[5] Rapid and precise diagnosis is essential for effective treatment. Our study aims to assess the clinical safety of ^{61}Cu-NuriPro™ and compare its diagnostic performance with an FDA-approved PSMA-targeting radiotracer. The first patient has not experienced any adverse events so far and the scan with ^{61}Cu-NuriPro™ showed more osseous lesions than ^{18}F-piflufolastat, at 1 hour post-injection. Also, the PET scans with ^{61}Cu-NuriPro™ identified more osseous lesions at 2 and 4 hours compared to 1 hour post-injection. These preliminary clinical findings are in accordance with the preclinical results and underline the potential, favorable imaging performance of ^{61}Cu-NuriPro™."

"With the initiation of this first trial, we have begun building the clinical data that aiming to demonstrate the differentiation of our radiopharmaceutical approach after our copper-based candidates have shown greater imaging capacity with less toxicity in pre-clinical studies. Copper's unique properties allow us to establish the first true theranostic pipeline that can achieve more accurate staging of the individual patient and more precise treatment of their disease," said **Leila Jaafar, PhD, CEO and Co-Founder of NUCLIDIUM**. "Our NuriPro™ diagnostic's imaging profile can overcome both detection and production challenges for physicians and patients living with prostate cancer and we look forward to further exploring its potential."

About NUCLIDIUM

NUCLIDIUM is transforming precision oncology with its state-of-the-art copper-based radiopharmaceuticals, delivering unmatched accuracy and accessibility for targeted cancer treatment and diagnosis. Our innovative platform merges copper radiometals with targeted cancer molecules, speeding up the creation of new diagnostic and therapeutic solutions. This portfolio enhances efficacy and safety, offering cost-effective solutions for hospitals and patients. Our unique true theranostic model simplifies development, tackling manufacturing and distribution challenges to increase flexibility for medical providers. Our diverse, interdisciplinary team is dedicated to revolutionizing precision radio-oncology, significantly benefiting cancer patients.

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[2] Heo YA, Jadvar H, Calais J, et al. Flotufolastat F 18: Diagnostic First Approval Appropriate Use Criteria for Prostate-Specific Membrane Antigen PET Imaging. *Mol Diagn Ther*. Jul 13; Jan 2023;63(1):59-68. doi:10.1007/s40291-023-00665-y10.2967/jnumed.121.263262

[3] FDA Approves Pluvicto/Locametz for Metastatic Castration-Resistant Prostate Cancer. *J Nucl Med*. May 2022;63(5):13n.

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[5] NIH: Cancer Stat Facts, https://seer.cancer.gov/statfacts/html/prost.html, accessed 15 October 2024.