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PeptiDream
Revolutionizing Drug Discovery

To the press

New Radiopharmaceuticals for Renal Cell Carcinoma

-Assessing the potential of PD-32766 as a PET diagnostic and raising expectations for novel diagnostic and therapeutic agents in nuclear medicine-

March 28, 2025
National Cancer Center
PeptiDream Inc.

Highlights

- The first-in-human PET imaging trial of ^{64}Cu-PD-32766 for patients with clear cell renal cell carcinoma (ccRCC) was conducted at the National Cancer Center Hospital East and promising results were obtained.
- PET positive rate: ^{64}Cu-PD-32766 was confirmed to clearly accumulate in the lesion sites, with a PET positive rate of 95% by lesion, suggesting promising utility as a diagnostic agent.
- Pharmacokinetics: Blood concentration of ^{64}Cu-PD-32766 dropped sharply within 5 minutes after administration, indicating good clearance from the bloodstream while maintaining accumulation in lesion sites.
- Safety: Demonstrated good tolerability with no serious side effects or adverse events.
- Implication for therapeutic development: Estimation of the absorbed dose when replacing ^{64}Cu with the therapeutic radionuclide ^{225}Ac suggests that the dose level is sufficient to achieve therapeutic effects.
- The results of the clinical trial were presented at ASCO Genitourinary Cancers Symposium 2025 held in February 2025.

Overview

The National Cancer Center (President: Hitoshi Nakagama, hereinafter “NCC”) Hospital East (Director: Toshihiko Doi), The National Cancer Center Exploratory Oncology Research & Clinical Trial Center (Director: Katsuya Tsuchihara, “EPOC”) and PeptiDream Inc., a public Kanagawa, Japan-based biopharmaceutical company (CEO: Patrick C. Reid, “PeptiDream”) (Tokyo: 4587) today announced promising results from the first-in-human[Note1] imaging trial of ^{64}Cu-PD-32766, a ^{64}Cu-labelled radiopharmaceutical targeting Carbonic Anhydrase IX (CA9), for patients with clear cell renal cell carcinoma (ccRCC). This trial, which was conducted at the NCC Hospital East in collaboration started from November 2023, aims for the early application of radiopharmaceuticals targeting CA9. The results showed that ^{64}Cu-PD-32766 effectively diagnosed tumors and in addition, calculations replacing ^{64}Cu with ^{225}Ac suggest that the absorbed dose in the tumor was 105.5±55.8 mGy/MBq, which is expected to be sufficient for therapeutic effect. These findings were

presented at the ASCO Genitourinary Cancers Symposium 2025 held in February 2025 (Poster Link).

Background

RCC is a disease with a poor prognosis, which necessitates the establishment of novel diagnosis and therapeutic methods. CA9 is a cell surface antigen highly expressed in ~95% of ccRCC with minimal expression in normal tissues, making it an attractive target for diagnosis and treatment. PeptiDream and its wholly owned subsidiary PDRadiopharma discovered and developed PD-32766. The objective of this trial was to evaluate the pharmacokinetics of PD-32766 labeled with ^{64}Cu, a diagnostic radionuclide, and assess its utility as a PET agent (JRCT trial identifier: jRCTs031240046).

Details

In this trial, ^{64}Cu-PD-32766, which was manufactured using NCC Hospital's ^{64}Cu production technologies and EPOC's radiopharmaceuticals manufacturing technologies, was administered to five patients with newly diagnosed, relapsed or suspected relapsed ccRCC at NCC Hospital East. The safety, pharmacokinetics and dosimetry of PET/CT imaging using ^{64}Cu-PD-32766 were evaluated.

The effective dose for whole body by administration of ^{64}Cu-PD-32766 was 0.102±0.0361 mSv/MBq and no serious side effects or adverse events were observed.

Accumulation of ^{64}Cu-PD-32766 in tumor lesions was confirmed by PET imaging within 5 minutes after administration, with positive rate of over 95% of lesions diagnosed by CT imaging. Clear PET images of tumor lesions were obtained from 5 minutes to 24 hours post-administration. The blood concentration of ^{64}Cu-PD-32766 rapidly decreased within 5 minutes after administration, confirming good clearance[Note2].

These results suggest the potential utility of ^{64}Cu-PD-32766 as a diagnostic agent for ccRCC. Furthermore, calculations replacing ^{64}Cu with the therapeutic radionuclide ^{225}Ac suggest that the absorbed dose in the tumor was 105.5±55.8 mGy/MBq, which is expected to be sufficient for therapeutic effects.

Outlook

This trial investigated the potential application of ^{64}Cu-PD-32766 as a diagnostic agent by evaluating safety, pharmacokinetics and whole-body absorbed dose. The results also suggest the potential theranostic[Note3] application of PD-32766 by using both diagnostic and therapeutic radionuclides such as ^{225}Ac. By evaluating the pharmacokinetics and targeted accumulation in tumors with a minimal dose administered to patients, this trial is anticipated to contribute to accelerating subsequent clinical development of PD-32766.

Comments of Dr. Toshihiko Doi, Director, National Cancer Center Hospital East

The results of this trial in which administering a very small dose of ^{64}Cu-PD-32766 to patients with ccRCC is sufficient to visualize the agent reach the tumor site within the patient's body holds significant implications. It expands the possibility of accurately predicting efficacy and safety at an early stage. Our mission, as a leading cancer center globally, is to provide patients with innovative treatments and improve medical care in Japan. Based on these results, we are hopeful that the combination of cancer-targeting peptides with specific radionuclides can be utilized to diagnose and treat many patients in addition to those with ccRCC.

Comments of Dr. Katsuya Tsuchihara, Director, National Cancer Center Exploratory Oncology Research & Clinical Trial Center

We are delighted that the radiopharmaceutical manufacturing technology developed at EPOC has contributed to the first-in-human study of ^{64}Cu-PD-32766. Our goal is to bridge novel medical technologies to early clinical trials and provide innovative treatments for patients. We continue to contribute to the acceleration of research and development of novel radiopharmaceuticals.

Comments of Dr. Patrick C. Reid, President & CEO of PeptiDream

We are excited to see the excellent results from the first-in-human study at NCC of PD-32766 which was discovered at PeptiDream to target CA9. We are aiming to utilize PD-32766, a macrocyclic peptide labelled with radionuclides such as ^{64}Cu, for diagnosis and treatment of patients with ccRCC. This accomplishment represents the collective effort of the PeptiDream Group and marks significant progress in our collaboration with NCC. Our group will continue to advance the development of radiopharmaceuticals using PD-32766 to make a significant impact on the treatment of cancer patients.

About Renal Cell Carcinoma (RCC)

RCC is the 9th most common cancer in the United States, representing 2% of all global cancer diagnoses and death, with 5-year survival rates at 17% (worldwide an estimated 430,000 people were diagnosed with kidney cancer in 2020, with roughly 9 out of 10 kidney cancers being renal cell carcinomas). There are largely three main types of RCC, clear cell (“ccRCC”), papillary (“pRCC”), and chromophobe (“chRCC”), with ccRCC representing roughly 70% of RCC cases.

About CA9 and PD-32766

CA9 is a cell surface antigen highly expressed in ~95% of ccRCC with minimal expression in normal tissues, making it a potentially ideal target for the diagnosis and treatment of ccRCC. PeptiDream discovered and developed PD-32766 using its proprietary Peptide Discovery Platform System (PDPS) technology, with in vivo imaging[Note4] and efficacy studies conducted by PDRadiopharma Inc., PeptiDream’s wholly owned subsidiary.

Reference

- First-in-human phase 0 safety, imaging, pharmacokinetics, and dosimetry study of 64Cu-PD-32766, a carbonic anhydrase IX (CAIX)-targeting peptide, in patients with clear cell renal cell carcinoma (ccRCC). (The 2025 ASCO Genitourinary Cancers Symposium)
- A novel Carbonic Anhydrase IX targeting radiopeptide, 64Cu-PD-32766 and 177Lu-PD32766, exhibit promising theranostic potential in ccRCC tumors. (American Association for Cancer Research (AACR) Annual Meeting 2024)

Glossary

(Note1) First-in-human

A study in which the drug is administered to a human for the first time is called a “first-in-human study”

(Note 2) Clearance

Rate at which the drug is eliminated from the body

(Note 3) Theranostics

A medical approach that integrates both treatment and diagnosis by using different nuclides for diagnosis and treatment based on the same targeting molecule, such as peptides. Theranostics makes it possible to perform cancer diagnosis and treatment in an integrated manner and is expected to have benefits such as effectively selecting patients who are most likely to benefit from treatment and being able to monitor the effectiveness of treatment at any time.

(Note 4) In vivo imaging

Observation of the behavior of administered compounds labeled with a radionuclide or other method. For example, in vivo imaging techniques can be used to visualize how a drug is distributed, metabolized, and excreted in the body when administered.

About National Cancer Center Hospital East

The National Cancer Center Hospital East (NCCHE), established in 1992, is a highly specialized cancer hospital committed to providing world-class cancer care and pioneering innovative treatments. Located in Kashiwa-no-ha, Chiba, an emerging hub for medical innovation driven by academia-industry collaboration, NCCHE works closely with the NCC Exploratory Oncology Research & Clinical Trial Center (NCC EPOC). Together, they advance the development of cancer drugs, medical devices, and personalized medicine including genomic medicine, achieving significant milestones through an international research network.
URL: https://www.ncc.go.jp/en/ncce/index.html

About National Cancer Center Exploratory Oncology Research & Clinical Trial Center

The mission of the National Cancer Center Exploratory Oncology Research & Clinical Trial Center

(NCC EPOC) is to advance research and development. As the landscape of pharmaceutical and medical device development evolves with open innovation, NCC EPOC aims to be an agile, adaptable organization that swiftly responds to changes and challenges in collaboration with other NCC units and domestic/international research institutions. NCC EPOC focuses on applied and early clinical research of promising, game-changing technologies including regenerative and cellular medicine, nuclear medicine, AI and robotics.
URL: https://www.ncc.go.jp/en/epoc/index.html

About PeptiDream Inc.

PeptiDream Inc. (Tokyo Stock Exchange Prime Market 4587) is leading the translation of macrocyclic peptides into a whole new class of innovative medicines to address unmet medical needs and improve the quality of life of patients worldwide. In its radiopharmaceutical business, through its wholly-owned subsidiary PDRadiopharma, PeptiDream markets and sells a number of approved radiopharmaceuticals and radiodiagnostics in Japan, as well as leveraging its proprietary Peptide Discovery Platform System (PDPS) technology to discover and develop a deep pipeline of innovative targeted radiotherapeutics and radiodiagnostics, spanning both wholly-owned internal programs and globally partnered programs. In its non-radiopharmaceutical business, PeptiDream is similarly leveraging PDPS to discover and develop a broad and diverse pipeline of investigational peptide therapeutics, peptide drug conjugates (PDC) and multi-functional peptide conjugates (MPC) across an extensive global network of discovery and development partners. PeptiDream is headquartered in Kawasaki, Japan. For more information about our company, science and pipeline, please visit www.peptidream.com.

Inquiries

- Study Inquiries／For patients

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