NCC and PeptiDream Announce the First Dosing of ^{64}Cu-PD-32766 in a patient with Clear Cell Renal Cell Carcinoma

June 4, 2024

National Cancer Center

PeptiDream Inc.

Highlights

- First-in-human PET imaging study of ^{64}Cu-PD-32766 for patients with clear cell renal cell carcinoma were initiated.
- By utilizing PET, the diagnostic capability of ^{64}Cu-PD-32766 as well as the potential for therapeutic efficacy when labeled with therapeutic isotopes (radiotheranostics[Note]) will be investigated.
- Clinical information generated in this study is expected to accelerate further clinical development in radiopharmaceuticals.

Overview

The National Cancer Center (President: Hitoshi Nakagama) Hospital East (Director: Toshihiko Doi) and PeptiDream Inc., a public Kanagawa, Japan-based biopharmaceutical company (President: Patrick C. Reid, hereinafter “PeptiDream”)(Tokyo: 4587) today announced the dosing of the first patient in the human imaging study of PeptiDream’s ^{64}Cu-PD-32766, a ^{64}Cu-labelled radiopharmaceutical targeting Carbonic Anhydrase IX (CAIX), for patients with clear cell renal cell carcinoma (ccRCC) conducted at the National Cancer Center Hospital East (“the clinical research”).

Details

The clinical research, which was approved by the National Cancer Center Japan’s clinical review board in April 2024, is a first-in-human imaging study of ^{64}Cu-PD-32766 conducted in collaboration with the National Cancer Center Japan and PeptiDream. This study is intended to evaluate the safety, pharmacokinetics, and accumulation of ^{64}Cu-PD-32766 in tumors using PET in patients with newly diagnosed, relapsed or suspected relapsed ccRCC.

Overview of Clinical Research

Title	Early-phase clinical trial of ^{64}Cu-PD-32766 for the patients with clear cell renal cell carcinoma
Principal Investigator	Anri Inaki (National Cancer Center Hospital East)
Objectives	To evaluate the safety, pharmacokinetics, and exposure dose of PET/CT test with ^{64}Cu-PD-32766 in patients with newly diagnosed, relapsed or suspected to have relapsed ccRCC.

Inclusion Criteria	Proven ccRCC patients with the presence of distant metastatic lesions (including distant metastatic recurrence) or local recurrence lesions from the site of removal after total nephrectomy of the diseased kidney
Number of Subjects	6
Primary outcome	Per-patient PET sensitivity
Secondary outcomes	Per-lesion PET sensitivity, safety, pharmacokinetics and estimated irradiation dose

JRCT trial identifier: jRCTs031240046

CAIX 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 and efficacy studies conducted by PDRadiopharma Inc. (PeptiDream's wholly owned subsidiary). Key advantages of this clinical research are the ability to generate early human imaging data (often referred to as a Phase 0 study) using diagnostic ^{64}Cu agent directly in the target patient population which provides an early look at the diagnostic usefulness of the agent, the likelihood of therapeutic benefit when labeled with a therapeutic radioisotope, and additional critical information that can be used in designing subsequent clinical studies, thereby significantly accelerating clinical development.

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

We are delighted to report the initiation of this human imaging study, with the first administration of ^{64}Cu-PD-32766 in patients diagnosed with ccRCC. As one of the leading cancer centers in Japan, our mission is to continuously improve healthcare in Japan, by bringing innovative life changing therapeutics to our patients in need, and we believe that combining PeptiDream's cancer targeting peptides with the imaging and cancer killing power of radionuclides, represents a highly promising new therapeutic approach toward the diagnosis and treatment of patients with ccRCC.

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

We are excited to announce that our collaborators at the National Cancer Center Japan have dosed the first patient in the human imaging study of PD-32766, our CAIX targeting macrocyclic peptide radiolabeled with ^{64}Cu, for the potential diagnosis and treatment of patients with ccRCC. I am extremely proud of the entire PeptiDream team, and grateful to our National Cancer Center Japan collaborators, for this wonderful achievement, and we look forward to sharing the results as they become available. We are deeply committed to utilizing our peptide expertise to develop the next generation of targeted radiopharmaceuticals, which we believe will have a tremendous impact on cancer patient care.

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 12% (worldwide an estimated 400,000 people were diagnosed with kidney cancer in 2020, with roughly 9 out of 10 kidney cancers being RCCs). There are largely three main types of RCC, clear cell ("ccRCC"), papillary ("pRCC-type 1 and type 2"), and chromophobe ("chRCC"), with ccRCC representing roughly 70% of RCC cases.

Reference

A novel Carbonic Anhydrase IX targeting radiopeptide, ^{64}Cu-PD-32766 and 177Lu-PD32766, exhibit promising theranostic potential in ccRCC tumors. (American Association for Cancer Research (AACR) Annual Meeting 2024)

Glossary

(Note) Radiotheranostics

Radiotheranostics refers to the use of radioisotope-labelled agents to diagnose and treat patients by using different nuclides. Theranostics integrate the diagnosis and treatment of cancer, narrow down patients who is likely to be effective in treatment and monitor the effectiveness of treatment.

Inquiries

- Study Inquiries／For patients

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About National Cancer Center Hospital East

At National Cancer Center Hospital East, we provide our patients with world-class cancer treatments, multidisciplinary teams consisting of various specialities coordinate the best support for each patient, delivered with utmost care. We offer advanced medical services using state-of-the art medical devices such as robot-assisted surgery, proton beam and endoscopic therapy, minimally

invasive surgery limiting burdens to the patient. We also provide various drug treatments and conduct many clinical trials.
URL: https://www.ncc.go.jp/jp/ncce/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.