To the press

Initial Post-Dose Analysis Conducted in First Patient in First-in-Human Study of ^{64}Cu-PD-29875, a Claudin18.2-Targeting Radiopharmaceutical Candidate

July 2, 2026

National Cancer Center

PeptiDream Inc.

Highlights

- A first-in-human clinical research for ^{64}Cu-PD-29875 is underway in patients with gastric cancer, and dosing and post-dose analysis have been completed.
- Initial analysis in the first patient showed no significant safety concerns, and provided encouraging findings regarding pharmacokinetics and tumor uptake to inform further evaluation.
- This study is designed to evaluate the diagnostic potential of ^{64}Cu-PD-29875, a ^{64}Cu-labeled radiopharmaceutical candidate targeting Claudin 18.2, and provide insights into its potential expansion into therapeutic radiopharmaceuticals using therapeutic radioisotopes.
- Clinical information generated from this research is expected to accelerate further clinical development of CLDN18.2-targeting radiopharmaceuticals.

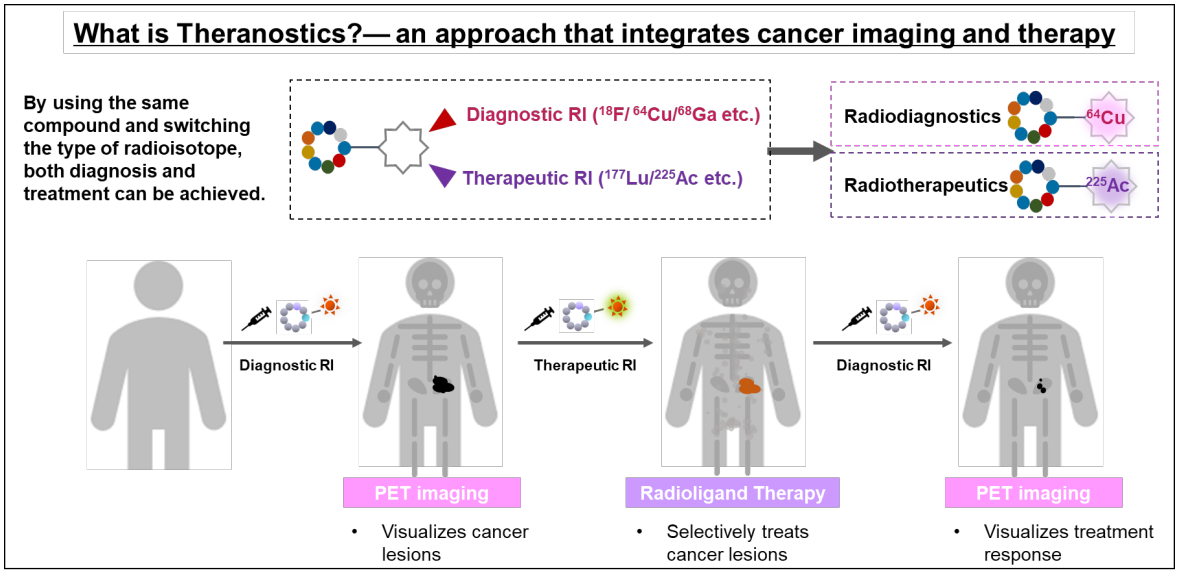
Overview

The National Cancer Center Japan (President: Hiroyuki Mano, Tokyo; hereinafter “NCC”) and PeptiDream Inc. (President: Patrick C. Reid, Headquarters: Kawasaki, Kanagawa; hereinafter “PeptiDream”) today announced that dosing of the first patient and subsequent post-dose analysis have been conducted in a first-in-human imaging study of ^{64}Cu-PD-29875, a ^{64}Cu-labeled radiopharmaceutical candidate targeting Claudin 18.2 (“CLDN18.2”), in patients with gastric cancer at National Cancer Center Hospital East (Director: Toshihiko Doi, Kashiwa, Chiba) (“clinical research”).

Details

This clinical research is a first-in-human Phase 0 imaging study*Note1 of ^{64}Cu-PD-29875 conducted under a research protocol approved by the clinical review board of National Cancer Center Hospital East in December 2025. In this study, ^{64}Cu-PD-29875, manufactured using radiopharmaceutical manufacturing technologies developed at the NCC Exploratory Oncology Research & Clinical Trial Center (Director: Katsuya Tsuchihara, “EPOC”), is administered to patients with gastric cancer, including gastroesophageal junction cancer and is evaluated using PET/CT imaging for the safety,

pharmacokinetics, tumor uptake, and dosimetry. In the initial evaluation following the first administration, no major safety concerns were observed. Findings related to pharmacokinetics and tumor uptake were obtained, supporting continued evaluation in this clinical research. This Phase 0 study is conducted prior to a Phase 1 clinical trial and involves the administration of microdoses of an investigational compound. PET imaging with ^{64}Cu-PD-29875 will enable assessment of its diagnostic performance and provide insights into its potential as a paired radiotherapeutic[*Note²] agent when labeled with therapeutic radioisotopes, thereby supporting the exploration of its theranostic potential and further clinical development.



Key details of the clinical research are as follows:

Title	First-in-human Phase 0 Study of a ^{64}Cu-Labeled Claudin18.2-Targeting Cyclic Peptide Drug in Patients with Gastric Cancer (CLAUDIRA-IIS)
Clinical Research Administrator	Anri Inaki (National Cancer Center Japan)
Objectives	To evaluate the efficacy, safety, pharmacokinetics, and dosimetry of PET/CT imaging using ^{64}Cu-PD-29875 in patients with gastric cancer, including esophagogastric junction cancer.
Inclusion Criteria	Patients with gastric cancer or gastroesophageal junction cancer with distant metastatic lesion, locally residual lesion, or recurrent lesion.
Number of Subjects	6
Primary outcome	Safety
Secondary outcomes	Lesion-based PET positivity rate, patient-based PET positivity rate, pharmacokinetics and estimated radiation dose

jRCT trial identifier: jRCTs031250563

CLDN18.2 is a member of the claudin family involved in tight junction formation and is highly expressed in a variety of solid tumors, including gastric cancer, esophageal cancer, pancreatic cancer and lung adenocarcinoma. It is regarded as an attractive molecular target for both cancer diagnosis and therapy.

PD-29875 is a macrocyclic peptide discovered using PeptiDream's proprietary PDPS® technology and further optimized through in vivo imaging*[Note3] and efficacy studies conducted at PDRadiopharma, a wholly owned subsidiary of PeptiDream.

By obtaining PET imaging data in this clinical research, early insights into the diagnostic performance of ^{64}Cu-PD-29875, as well as its potential application in therapeutic radiopharmaceuticals labeled with therapeutic radioisotopes, are expected to be gained, thereby accelerating clinical development.

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

We are pleased to announce the initiation of this first-in-human imaging study with the initial administration of ^{64}Cu-PD-29875 in patients with gastric cancer. In the first patient, PET imaging using ^{64}Cu-PD-29875 demonstrated favorable safety, pharmacokinetics, and tumor uptake. Further evaluation will continue through the clinical research. As one of Japan's leading cancer centers, our mission is to continuously improve healthcare by delivering innovative, life-changing therapies to patients in need. We believe that combining PeptiDream's cancer targeting peptides with the diagnostic and therapeutic capabilities of radionuclides represents a highly promising new therapeutic and diagnostic approach for patients with a wide range of cancers, including gastric cancer.

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

We are delighted that the radiopharmaceutical manufacturing technologies developed at EPOC have contributed to this first-in-human imaging study of ^{64}Cu-PD-29875. Our mission at EPOC is to bridge innovative medical technologies to early-stage clinical trials and bring breakthrough treatments to patients. We will continue to actively contribute to accelerating the research and development of novel radiopharmaceuticals.

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

We view the dosing of the first patient in the clinical study of PD-29875, our second internally developed radiopharmaceutical program, as an important milestone. PD-29875 is a macrocyclic peptide that selectively binds to CLDN18.2, an emerging and highly attractive cancer target. We position PD-29875 as a core asset in our radiotheranostic approach, including plans to develop both a ^{225}Ac-labeled therapeutic and a ^{64}Cu-labeled diagnostic. Leveraging our peptide expertise,

we remain deeply committed to advancing the next generation of targeted radiopharmaceuticals to improve cancer patient care.

PD-29875 was adopted by the Japan Agency for Medical Research and Development (AMED) as part of the “Practical Research for Innovative Cancer Control” and received funding support from AMED in 2024.

About Gastric Cancer and Gastroesophageal Junction Cancer

Gastric cancer is the fifth most common cancer worldwide and the fourth leading cause of cancer death, accounting for approximately 7% of global cancer diagnoses. It is known for its poor prognosis, with a 5-year survival rate of around 32%. In 2020, an estimated 1.10 million people worldwide were diagnosed with stomach cancer, and about 770,000 patients died from the disease. The number of gastric cancer cases is projected to rise to roughly 1.8 million in 2040. Gastroesophageal junction cancer, which occurs at the junction of the esophagus and stomach, has shown an increasing incidence in recent years. Similar to gastric cancer, expression of CLDN18.2 is frequently observed in gastroesophageal junction tumors, making it a promising molecular target in both cancers.

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) 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 3) 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.

Related Release

New Radiopharmaceuticals for Renal Cell Carcinoma | National Cancer Center/ PeptiDream
https://www.ncc.go.jp/en/information/press_release/2025/0328/index.html

About the National Cancer Center Hospital East

The National Cancer Center Hospital East, 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, National Cancer Center Hospital East works closely with the National Cancer Center Exploratory Oncology Research & Clinical Trial Center. Together, they advance the development of cancer drugs, medical devices, and personalized medicine including genomic medicine, achieving significant milestones through an international research network.

About National Cancer Center Exploratory Oncology Research & Clinical Trial Center

The mission of the National Cancer Center Exploratory Oncology Research & Clinical Trial Center (EPOC) is to advance research and development. As the landscape of pharmaceutical and medical device development evolves with open innovation, EPOC aims to be an agile, adaptable organization that swiftly responds to changes and challenges in collaboration with other National Cancer Center Japan units and domestic/international research institutions. EPOC focuses on applied and early clinical research of promising, game-changing technologies including regenerative and cellular medicine, nuclear medicine, AI and robotics.

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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