



December 11, 2025

PeptiDream Inc.
<https://www.peptidream.com/en/>
 (TSE Prime Market: 4587)

Approval of Clinical Research Protocol for ⁶⁴Cu-PD-29875, a Claudin 18.2-Targeting Radiopharmaceutical, in Patients with Gastric Cancer

KANAGAWA, JAPAN – December 11, 2025 - PeptiDream Inc., a public Kanagawa, Japan-based biopharmaceutical company (President: Patrick C. Reid, hereinafter "PeptiDream")(Tokyo Stock Exchange: 4587) today announced that a specified clinical research study*1 for ⁶⁴Cu-PD-29875, a ⁶⁴Cu-labelled radiopharmaceutical targeting Claudin 18.2 (CLDN18.2) at the National Cancer Center Japan (President: Hiroyuki Mano), for patients with gastric cancer has been approved by the clinical review board of the National Cancer Center Hospital East (Director: Toshihiko Doi).

PD-29875 is the second internal peptide radiopharmaceutical development candidate arising from the PeptiDream's internal discovery and development efforts (please refer to "[PeptiDream Announces Second Internal Peptide Radiopharmaceutical Therapeutic Program Targeting Claudin 18.2 for the Potential Diagnosis and Treatment of Gastric Cancer](#)"). This specified clinical research is intended to evaluate the safety, pharmacokinetics, and accumulation of the radiodiagnostic agent ⁶⁴Cu-PD-29875 in tumors using PET imaging in patients with gastric cancer including esophagogastric Junction (EGJ) cancer. A brief overview of the specified clinical research is as follows;

[Overview of Specified Clinical Research]

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)
Sponsor	Anri Inaki (Exploratory Oncology Research & Clinical Trial Center, National Cancer Center Japan)
Objectives	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

*: JRCT trial identifier: jRCTs031250563

*1: For details of the specified clinical research, please refer to the MHLW web site (Clinical Trials Act).

PD-29875 is a macrocyclic peptide discovered using PeptiDream's proprietary PDPS® technology and further optimized at PeptiDream with in vivo imaging and efficacy studies conducted at PDRadiopharma, our wholly owned subsidiary. PeptiDream plans to develop PD-29875 as a theranostic agent, pairing the radiotherapeutic (²²⁵Ac-PD-29875) with the diagnostic imaging agent (⁶⁴Cu-PD-29875) for the diagnosis and treatment of gastric cancer.

A key advantage of this specified clinical research is the ability to generate early human imaging data (often referred to as a Phase 0 study) using ⁶⁴Cu-labeled 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.

PD-29875 was adopted by the Japan Agency for Medical Research and Development (AMED) as part of the “Practical Research for Innovative Cancer Control” (Project Name: Development of Claudin18.2 targeting peptide as theranostics for diagnosis and treatment of gastric cancer, Principal Investigator: Anri Inaki) and received funding support from AMED to conduct clinical development activities.

About CLDN18.2

CLDN18.2 is a tight junction protein normally and specifically expressed in gastric mucosa cells. The expression of CLDN18.2 is sustained during the malignant transformation of gastric mucosa, and its epitopes become exposed on the surface of GC cells due to the loss of cell polarity. Therefore, CLDN18.2 is considered a promising therapeutic target for GC. CLDN18.2 is expressed in a variety of solid tumors, including gastric cancer, pancreatic cancer, biliary cancer, genitourinary tract cancers, and colorectal cancer, and others.

About Gastric and EGJ cancer

Gastric cancer is the 5th most common cancer in and the 4th leading cause of cancer death worldwide in 2020, representing 7% of all global cancer diagnoses, with an approximate 5-year survival rate of 32% (worldwide an estimated 1.1 million people were diagnosed with gastric cancer in 2020, with 770,000 deaths), with the incidence expected to increase to ~1.8 million new cases per year by 2040. Gastroesophageal junction cancer is a malignancy that arises at the junction between the esophagus and the stomach, and its incidence has been increasing in recent years. Similar to gastric cancer, expression of CLDN18.2 is observed in these tumors.

About PeptiDream Inc.

PeptiDream Inc. (Tokyo Stock Exchange Prime Section 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/en/

Inquiries:

PeptiDream Inc.

Contact: Yuko Okimoto, IR & Public Affairs

Email: info@peptidream.com

Website: <https://www.peptidream.com/en/>

X: <https://x.com/PeptidreamInc>