



December 22, 2025

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

PeptiDream Announces FDA Clearance of IND Applications for Phase 1 Clinical Trials of ²²⁵Ac-PD-32766 and ⁶⁴Cu-PD-32766 in Patients with Kidney Cancer

KANAGAWA, JAPAN – December 22, 2025 - PeptiDream Inc., a public Kanagawa, Japan-based biopharmaceutical company (President: Patrick C. Reid, hereinafter "PeptiDream")(Tokyo Stock Exchange: 4587) today announced that the U.S. Food and Drug Administration (FDA) has granted the Investigational New Drug (IND) clearance for the Phase 1 clinical trials of ²²⁵Ac-PD-32766, as a potential radiotherapeutic, and ⁶⁴Cu-PD-32766 as the radiodiagnostic pair for patients with clear cell renal cell carcinoma (ccRCC).

PD-32766 is a macrocyclic peptide targeting Carbonic Anhydrase IX (CA9) conjugated to a chelator radiolabeled with Actinium 225 (²²⁵Ac) (for the therapeutic; PD-32766T) or Copper 64 (⁶⁴Cu) (for the diagnostic; PD-32766D). PD-32766 was discovered using PeptiDream's proprietary PDPs® technology and further optimized at PeptiDream with in vivo imaging and efficacy studies conducted at PDRadiopharma. 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.

A Ph0 Imaging Study/Clinical Research of ⁶⁴Cu-PD-32766, a ⁶⁴Cu-labelled radiodiagnostic agent targeting CA9, was previously conducted at the National Cancer Center Japan (President: Hiroyuki Mano) Hospital East (Director: Toshihiko Doi). The study demonstrated that ⁶⁴Cu-PD-32766 clearly accumulated in tumors and the absorbed dose was expected to be sufficient for therapeutic effect. The results of the Ph0 study were presented at the American Society of Clinical Oncology's (ASCO) Genitourinary Cancers Symposium (ASCO-GU 2025) in February 2025. (please refer to "[New Radiopharmaceuticals for Renal Cell Carcinoma](#)"). Additionally, PeptiDream presented preclinical results for the PD-32766 CAIX Program at the recent Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting on June 21, 2025 in New Orleans as well as the Annual Congress of the European Association of Nuclear Medicine (EANM) on October 5, 2025 in Barcelona.

The Phase 1 Study will investigate the safety, tolerability, and dosimetry of ²²⁵Ac-PD-32766 and ⁶⁴Cu-PD-32766 in patients with ccRCC.

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 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>