News Release

November 5, 2024

PDRadiopharma Inc.

# PDRadiopharma Inc. Receives "Controlled Medical Device" Certification for Brain Imaging Analysis Program "AMYclz® Neuro"

**This release is an English translation of "脳画像解析プログラム「AMYclz®ニューロ」「管理医療機器」の認証取得に関するお知らせ", with a priority given to Japanese for content and interpretation.*

TOKYO, JAPAN – November 5, 2024 - PDRadiopharma Inc. (President: Masato Murakami, Headquarters: Chuo-ku, Tokyo) announces that its brain imaging analysis program, "AMYclz® Neuro" has received certification as a "Controlled Medical Device."

This certification was granted by a registered certification body under the Ministry of Health, Labour, and Welfare in compliance with Japan's Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices.

The AMYclz® Neuro Program is designed to assist physicians in analyzing amyloid PET images obtained from a PET scan using PDRadiopharma's AMYViD ® Injection*. By providing objective information on amyloid-β accumulation, The AMYclz® Neuro aids clinicians in assessing patients with cognitive impairment who may be at risk for Alzheimer's disease.

Key Features of the AMYclz® Neuro Program

① **Image Overlay**: The Program overlays the patient's amyloid PET and MRI images, highlighting areas of amyloid-β accumulation to assist in precise location assessment.

② **Objective Measurement**: Quantitative indicators, such as the SUVr and centroid scale, are calculated from amyloid PET images to objectively assess the degree of amyloid-β accumulation.

③ **Reference Image Database**: The Program enables physicians to compare the patient's amyloid PET images against a comprehensive reference database, providing distribution and statistical information on amyloid-β accumulation in an easily visualized format.

The AMYclz® Neuro Program will be available to medical institutions utilizing AMYViD® Injection upon request for integration into clinical settings.

PDRadiopharma Inc. not only develops, manufactures, and markets therapeutic radiopharmaceuticals but also enhances radiopharmaceutical diagnostics with advanced imaging analysis programs.

By actively advancing solutions that support precise diagnosis and treatment, we are committed to improving dementia care, supporting a society focused on health and longevity, and bringing meaningful assistance to patients, their families, and the broader community affected by dementia.

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* Generic name: florbetapyr ($^{18}$F). AMYViD® Injection is a PET imaging agent developed to visualize amyloid beta plaques in the human brain with $^{18}$F-labbelled florbetapir as the active ingredient. It obtained marketing authorization in December 2016 as the first flexible-doseTM formulation which differs from conventional radiopharmaceuticals in Japan. AMYViD® is a registered trademark of Avid Radiopharmaceuticals,Inc.

**About PDRadiopharma**

PDRadiopharma, a wholly-owned subsidiary of PeptiDream from 2022, has been providing high-quality radiopharmaceuticals through the research and development, manufacturing, regulatory and sales as a forerunner in the field of radiopharmaceuticals, since it started its business in 1968. Currently PDRadiopharma offers 21 radiodiagnostic products (spanning both SPECT and PET products) and 8 radiotherapeutic products (3 product categories) in Japan. Additionally, PDRadiopharma and PeptiDream are developing a broad pipeline of radiotherapeutics and radiodiagnostics for both the Japan and global markets. For more information about PDRadiopharma, please visit www.pdradiopharma.com .

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