News Release

December 27, 2024

PDRadiopharma Inc.

Regulatory Approval for Tauvid® ,a PET Imaging Agent

**This release is an English translation of "PET 検査用イメージング剤「タウヴィッド®静注」製造販売承認取得のお知らせ", with a priority given to Japanese for content and interpretation. The indication is specifically for Japan only and not for other countries.*

TOKYO, JAPAN – December 27, 2024 – PDRadiopharma Inc. (President: Masato Murakami, Headquarters: Chuo-ku, Tokyo, Japan) announced today that that it has received approval from the Ministry of Health, Labour and Welfare for the drug regulatory approval of Tauvid® for the indication of " To support proper use of donanemab (genetical recombination) in patients with mild cognitive impairment and mild dementia due to Alzheimer's disease".

Tauvid® is a PET imaging agent that contains radioactive fluorine (^{18}F) to label florotauhipir, a low-molecular compound that binds to the tau protein associated with Alzheimer's disease. Tauvid® obtained approval in the United States in May 2020 for the indication to estimate the density and distribution of aggregated tau neurofibrillary tangles in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease, and it was also approved in Europe for the similar indication in August 2024.

In accordance with the joint development agreement signed with Eli Lilly and Company in 2022 for the Japanese market, PDRadiopharma has filed the marketing application based on the results of a global Phase 3 clinical trial of donanemab, which was recently listed on National Health Insurance (NHI) Drug Price Standard in Japan, and obtained regulatory approval today.

With the number of dementia patients rapidly increasing due to an aging population, the field of dementia treatment is entering a new era with the emergence of novel therapeutics. PDRadiopharma is committed to contribute to the advancement of dementia treatment through innovative diagnostic solutions, aiming improve outcomes for patients and support their families.

Product Overview

- Product name: TAUVID ®
- Generic name: flortaucipir F 18 injection
- Indication: To support proper use of donanemab (genetical recombination) in patients with mild cognitive impairment and mild dementia due to Alzheimer's disease.

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 23 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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