

November 20, 2024



PDRadiopharma Inc.

Expansion of Insurance Coverage of AMYViD[®], a PET Imaging Agent for Detecting Beta Amyloid

**This release is an English translation of “アミロイドPET 検査用イメージング剤「アミヴィット[®] 静注」 保険適用の範囲拡大に関するお知らせ”, with a priority given to Japanese for content and interpretation. The indication is specifically for Japan only and not for other countries.*

TOKYO, JAPAN – November 20, 2024 – PDRadiopharma Inc. (President: Masato Murakami, Headquarters: Chuo-ku, Tokyo, Japan) announced today that as of November 20, the precautions for positron emission tomography (PET) using the amyloid imaging agent "AMIVID[®] Injection" (generic name: florbetapir (¹⁸F)) have been updated, resulting in an expanded scope of insurance coverage.

- Product name: AMYViD[®] Injection
- Indication:
 - Visualization of beta amyloid plaques in the brain of patients with mild cognitive impairment or suspected to have dementia due to Alzheimer's disease.
 - Visualization of beta amyloid plaques in the brain of the patients administered monoclonal antibodies directed against beta amyloid.

AMIVID[®] Injection is the first PET imaging agent approved in Japan in December 2016 for the visualization of beta amyloid plaques in the brain of patients with cognitive impairment suspected to be due to Alzheimer's disease. Until now, insurance coverage was limited to its use in determining to administer anti-amyloid beta antibodies.

The latest expansion in insurance coverage now includes the evaluation of amyloid beta plaque removal following administration of anti-amyloid beta antibodies, as per the Ministry of Health, Labour and Welfare's optimal use guidelines. This coverage enables the use of AMIVID[®] Injection to assess whether to discontinue treatment or decide on treatment continuation beyond 18 months.

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.

About AMYVID® Injection (generic name: florbetapir (¹⁸F))

AMYVID® Injection is a PET imaging agent developed to visualize amyloid beta plaques in the human brain with ¹⁸F-labelled florbetapir as the active ingredient. It obtained marketing authorization in December 2016 as the first flexible-dose™ 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

Inquiries:
PDRadiopharma Inc.
Contact: Noriko Tanaka, General Affairs
Email: s-info-hq@pdradiopharma.com