

September 3, 2024



PDRadiopharma Inc.

Approval of Partial Change to the Indication 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」の効能又は効果の一部変更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 – September 3, 2024 - PDRadiopharma Inc. (President: Masato Murakami, Headquarters: Chuo-ku, Tokyo, Japan) today announced that it has received approval for a partial change (indication expansion) of AMYViD[®] Injection (generic name: florbetapir (¹⁸F)) for the following additional indication on August 29.

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.

(Changes underlined)

AMYViD[®] 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 have Alzheimer's disease. In August 2023, this indication was expanded to patients exhibiting even mild cognitive impairment or suspected to have dementia due to Alzheimer's disease.

With this additional indication expansion, patients treated with anti-amyloid beta antibodies will also be eligible to receive AMYViD[®] Injection to confirm the accumulation of beta amyloid plaques in the brain by PET imaging.

PDRadiopharma is committed to contribute to the advancement of dementia treatment by providing innovative diagnostics and will continue to support patients suffering from dementia and their families.

* PET: Positron Emission Tomography

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.

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