

August 31, 2023



PDRadiopharma Inc.

## Approval of partial change to the indication of AMYViD<sup>®</sup>, 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 – August 31, 2023 - PDRadiopharma Inc. (President: Susumu Tanahashi, Headquarters: Chuo-ku, Tokyo, Japan) today announced that the company has received approval for a partial change to the manufacturing and marketing authorization of AMYViD<sup>®</sup> Injection (generic name: florbetapir (<sup>18</sup>F)) in Japan for the following indication:

### 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.

(Changes underlined)

AMYViD<sup>®</sup> 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. With this indication expansion, patients exhibiting even mild cognitive impairment or suspected to have dementia due to Alzheimer's disease, will be eligible to receive AMYViD<sup>®</sup> Injection to confirm the accumulation of beta amyloid plaques in the brain by PET imaging.

In the United States, a new, disease modifying, therapeutic agent that directly addresses the underlying cause of Alzheimer's disease and slows down disease progression has been approved and in Japan, the First Committee on Drugs of the Ministry of Health, Labour and Welfare recommended approval of the therapeutic according to news reports. Confirmation of the accumulation of beta amyloid plaques in the brain is required to identify patients who are eligible to be treated with these disease-modifying agents, and diagnostics such as AMYViD<sup>®</sup> can be used for such confirmation.

Through the development of diagnostics that lead to treatment, we aim to expand the treatment options for Alzheimer's disease and contribute to the advancement of dementia treatment and to support patients suffering from dementia and their families in a society of healthy longevity.

**About AMYViD® Injection (generic name: florbetapir(18F))**

AMYViD® Injection 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 has been providing high-quality radiopharmaceuticals since it started its business in 1968. Our vision is to shine the lives through innovative diagnostics and therapeutics using radiopharmaceuticals. Currently, we domestically market 22 SPECT diagnostics, 2 PET diagnostics, and 8 therapeutic drugs (3 product categories). For more information, please visit <https://www.pdradiopharma.com/>

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