Press Release

IBA, CMI and Life Molecular Imaging announce Japanese approval for the reimbursement of amyloid-PET diagnostic Neuraceq® in Alzheimer's disease

Louvain-la-Neuve, Belgium, 13 December, 2023 – IBA (Ion Beam Applications S.A., EURONEXT), CMI Inc. and Life Molecular Imaging (LMI) are pleased to announce that the Japanese Ministry of Health has approved the reimbursement by governmental health insurance of the amyloid Positron Emission Tomography (PET) diagnostic Neuraceq® (florbetaben 18F).

Amyloid-PET imaging using agents like Neuraceq® is used in the diagnosis of Alzheimer's disease and other forms of cognitive impairment. It detects amyloid plaques in the brain, which are characteristic markers of Alzheimer's disease. With this approval, Neuraceq® is the first amyloid PET diagnostic tool reimbursed in Japan. Neuraceq® is produced with IBA's Synthera®+, a fully automated synthesizer optimized for the production of florbetaben 18F.

With the reimbursement of this diagnostic tool, Japanese physicians can use this state-of-the-art imaging technology to accurately evaluate their patients with cognitive decline. The density of amyloid plaques can be assessed to improve an earlier diagnosis, and to further guide therapy and patient management.

Amyloid PET, including Neuraceq®, had a pivotal role in the recent positive clinical study outcomes of new anti-amyloid drugs by making selective inclusion of patients with confirmed amyloid pathology in the brain. Moreover, amyloid clearance was precisely measured with amyloid PET.

Bruno Scutnaire, President of IBA RadioPharma Solutions commented, "*We are thrilled to join forces with these esteemed companies and celebrate this groundbreaking advancement in Alzheimer's disease diagnosis. We firmly believe this marks the initial stride towards establishing worldwide access to comprehensive care for this condition.*"

Dr. Ludger Dinkelborg, Managing Director of Life Molecular Imaging added, *"Achieving reimbursement for amyloid PET using Neuraceq® in Japan is a notable milestone. We are pleased that our amyloid PET tracer, a very important and reliable diagnostic imaging agent, is now available for more Japanese patients."*

Yasuhisa Fujibayashi, Chief Technology Officer, CMI Inc, commented, *"CMI is intensively working for PET facilities in Japan and we are encouraging them to deliver amyloid-PET using Neuraceq® to patients with possible Alzheimer's disease so that they may have an opportunity to access advanced therapeutic drugs."*

ENDS

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Life. Science.

About Neuraceq® (florbetaben 18F)

Neuraceq® is a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of the brain to estimate β-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline. Neuraceq® is available in Japan from the approved medical device Synthera®+. A negative Neuraceq® scan indicates sparse to no neuritic plaques and is inconsistent with a neuropathological diagnosis of AD at the time of image acquisition; a negative scan result reduces the likelihood that a patient's cognitive impairment is due to AD. A positive Neuraceq® scan indicates moderate to frequent amyloid neuritic plaques; neuropathological examination has shown this amount of amyloid neuritic plaque is present in patients with AD but may also be present in patients with other types of neurologic conditions as well as older people with normal cognition. Neuraceq® is an adjunct to other diagnostic evaluations.

Limitations of Use

- A positive Neuraceq® scan does not establish the diagnosis of AD or any other cognitive disorder.
- Safety and effectiveness of Neuraceq® have not been established for (i) predicting development of dementia or other neurologic conditions, or (ii) monitoring responses to therapies.

Important Safety Information (as approved in Japan)

Risk for Image Interpretation and Other Errors

Errors may occur in the Neuraceq® estimation of brain neuritic β-amyloid plaque density during image interpretation. Image interpretation should be performed independently of the patient's clinical information. Errors may also occur in cases with severe brain atrophy that limits the ability to distinguish gray and white matter on the Neuraceq® scan. Errors may also occur due to motion artifacts that result in image distortion. Neuraceq® scan results are indicative of the presence of brain neuritic β-amyloid plaques only at the time of image acquisition and a negative scan result does not preclude the development of brain neuritic β-amyloid plaques in the future.

Radiation Risk

Neuraceq®, similar to other radiopharmaceuticals, contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. Ensure safe handling to protect patients and health care workers from unintentional radiation exposure.

Common Adverse Reactions

The overall safety profile of Neuraceq® is based on data from 1,090 administrations of Neuraceq® to 872 subjects. Adverse Reactions occurring with a frequency of more than 1% include injection/application site erythema, injection site irritation and injection site pain.

For more information please visit: https://neuraceq.com

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About Life Molecular Imaging (LMI)
Life Molecular Imaging (LMI, formerly Piramal Imaging) was formed in 2012 with the acquisition of the molecular imaging research and development portfolio of Bayer Pharma AG. It is now part of the Life Healthcare Group. By developing novel PET tracers for molecular imaging, LMI is focusing on a key field of modern medicine. The organization strives to be a leader in the Molecular Imaging field by developing innovative products that improve early detection and characterization of chronic and life-threatening diseases, leading to better therapeutic outcomes and improved quality of life. Please visit https://life-mi.com.

About CMI Inc.
CMI Inc imports and sells highest quality products such as cyclotron system, automatic PET drug synthesizer, auto dispensing system and so on. CMI also supports planning, development and operation of clinical as well as research facilities for Positron Emission Tomography (PET) and contributes to the progress and expansion of Japanese medical field. Learn more at https://www.cmi-jpn.co.jp

About IBA
IBA (Ion Beam Applications S.A.) is the world leader in particle accelerator technology. The company is the leading supplier of equipment and services in the field of proton therapy, considered to be the most advanced form of radiation therapy available today. IBA is also a leading player in the fields of industrial sterilization, radiopharmaceuticals and dosimetry. The company, based in Louvain-la-Neuve, Belgium, employs approximately 2,000 people worldwide. IBA is a certified B Corporation (B Corp) meeting the highest standards of verified social and environmental performance.

IBA is listed on the pan-European stock exchange EURONEXT (IBA: Reuters IBAB.BR and Bloomberg IBAB.BB).

More information can be found at: www.iba-worldwide.com

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