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Media Contacts:

Christine Stergiou
JFK Communications
cstergiou@jfkhealth.com
(609) 456-0822

Nicole Fletcher
Piramal Imaging
nicole.fletcher@piramal.com
(857) 202-1122

Piramal Imaging Announces Strategic Partnership with PET Pharm Biotech for Exclusive Commercialization of NeuraCeq™ in Taiwan

BERLIN/BOSTON, September 6, 2016 – Piramal Imaging SA and PET Pharm Biotech Co. Ltd today announce the companies have entered into a strategic partnership and licensing agreement to provide PET Pharm Biotech with exclusive rights to manufacture, market, and distribute NeuraCeq (florbetaben F18 injection), throughout Taiwan. NeuraCeq is a radiopharmaceutical tracer for Positron Emission Tomography (PET) imaging of patients being evaluated for Alzheimer’s disease (AD) and other causes of cognitive impairment.

Alzheimer’s disease, a condition that slowly destroys memory and cognitive abilities, currently affects more than 190,000 people in Taiwan according to Taiwan’s Consumers Foundation. Until today, an estimated 20-30% of patients with dementia have been misdiagnosed and often experienced extended diagnostic episodes before receiving a clinical diagnosis.¹ Historically, a definitive diagnosis of Alzheimer’s disease could only be made after death based on autopsy findings of beta-amyloid plaques and neurofibrillary tangles in the brain after death. Today, a comprehensive clinical evaluation in combination with in-vivo biomarkers, such as beta-amyloid PET imaging, improves the diagnostic accuracy while the patient is still alive, allowing for optimal patient management and better health outcomes.

“We are confident that our commitment to providing access to diagnostic beta-amyloid radiotracers in Taiwan will have a significant impact on the management of patients suspected of having Alzheimer’s disease,” said Chih-Hao K. Kao, Chairman of the Board of Directors at PET Pharm Biotech. “In the context of evidence-based medicine, the introduction of NeuraCeq in the marketplace will offer a new clinical evaluation method for patients, physicians and caregivers alike in the diagnosis and management of Alzheimer’s disease. It could potentially help identify more efficacious interventions to help prevent, halt or slow down this terrible disease. PET Pharm Biotech is currently applying for a marketing authorization with the Taiwanese FDA.”

“Piramal Imaging continues to expand its manufacturing and distribution network to bring NeuraCeq into new markets,” said Ludger Dinkelborg, Member of the Board, Piramal Imaging. “The partnership with PET Pharm Biotech demonstrates our commitment to further expanding our global presence and increasing access to beta-amyloid PET scanning for imagers and referring physicians to advance the accuracy of clinical diagnosis in Alzheimer’s disease.”

About NeuraCeq (florbetaben F18 injection)

Indication

NeuraCeq™ is indicated for Positron Emission Tomography (PET) imaging of the brain to estimate beta-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.

A negative NeuraCeq™ scan indicates sparse to no amyloid 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:
 - Predicting development of dementia or other neurologic conditions;
 - Monitoring responses to therapies.

Important Safety Information

Risk for Image Interpretation and Other Errors

NeuraCeq™ can be used to estimate the density of beta-amyloid neuritic plaque deposition in the brain. NeuraCeq™ is an adjunct to other diagnostic evaluations. NeuraCeq™ images should be interpreted independent of a patient's clinical information. Physicians should receive training prior to interpretation of NeuraCeq™ images. Following training, image reading errors (especially false positive) may still occur. Additional interpretation errors may occur due to, but not limited to, motion artifacts or extensive brain atrophy.

Radiation Risk

Administration of 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. It is important to ensure safe handling to protect patients and health care workers from unintentional radiation exposure.

Most Common Adverse Reactions

In clinical trials, the most frequently observed adverse drug reactions in 872 subjects with 978 NeuraCeq™ administrations were injection/application site erythema (1.7%), injection site irritation (1.2%), and injection site pain (3.9%).

About Piramal Imaging SA

Piramal Imaging SA, a division of Piramal Enterprises, Ltd., was formed in 2012 with the acquisition of the molecular imaging research and development portfolio of Bayer Pharma AG. By developing novel PET tracers for molecular imaging, Piramal Imaging is focusing on a key field of modern medicine. Piramal Imaging 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. For more information please go to www.piramal.com/imaging.

About PET Pharm Biotech

PET Pharm Biotech Co., Ltd. was incorporated in 2011 with its head office and manufacturing site in Taipei, Taiwan. As a premium producer of PET drugs for clinical use, PET Pharm Biotech is focusing on commercialization of newly developed PET tracers and other radiopharmaceuticals for the benefit of Taiwan's 23 million people. It is thus the best choice of a partner for international developers to introduce their innovative radiopharmaceuticals into Taiwan and other regional markets. For more information please go to www.petpharmbio.com.

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¹ Speechly CM, Bridges-Webb C, Passmore E. The pathway to dementia diagnosis. Med J Aust. 2008;189(9):487-9.