

Press Release

First Site in Europe Begins to Offer Commercial Scans Using Piramal Imaging's NeuraCeq™ for Beta-Amyloid Plaque Imaging

Milestone for Dementia Diagnosis and Molecular Imaging

Cambridge, UK/Cologne, Germany, August 4, 2014 – Piramal Imaging announced today that the Clinic of Nuclear Medicine at the University of Cologne, Germany, is the first center in the world to perform NeuraCeq™ PET imaging scans on patients outside of clinical research studies. Availability of NeuraCeq™ began on July 22, marking the first time patients were able to receive a NeuraCeq scan at the request of a referring physician.

NeuraCeq, which received marketing authorization in the European Union and in the United States earlier this year, is a radiopharmaceutical 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 beta-amyloid scan may help rule out AD as a cause of a patient's cognitive decline. 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. Prior to the availability of this technology a confirmation of the clinical diagnosis of AD could only be accomplished through autopsy.

NeuraCeq is authorized by the European Commission. NeuraCeq scans will be available at selected PET imaging centers in Germany with plans for expanding patient access across Germany throughout the year.

"It is great to have a beta-amyloid tracer available for use with our patients," said Prof. Dr. Alexander Drzezga, Director of the Clinic for Nuclear Medicine at the University of Cologne, Germany. "For us as clinicians, beta-amyloid imaging with a targeted tracer such as NeuraCeq is a valuable new instrument for improving dementia diagnosis and patient assessment. This new imaging tool may also help patients and their families to gain more certainty and to plan for their future."

"With the launch of NeuraCeq in Germany, we've begun to widen the access to beta-amyloid imaging, taking a major step in defining and refining the role of such testing to support the selection of appropriate treatment options and improving outcomes for patients with cognitive impairment," said Friedrich Gause, Chief Operating Officer Piramal Imaging. "We're moving quickly to get NeuraCeq into the hands of experienced clinicians who diagnose and manage patients suspected of AD and dementia, underscoring Piramal Imaging's commitment to advancing the state of the art in dementia diagnosis and molecular imaging."

About NeuraCeq

Indication

This medicinal product is for diagnostic use only.

NeuraCeq is a radiopharmaceutical indicated for Positron Emission Tomography (PET) imaging of beta-amyloid neuritic plaque density in the brains of adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) and other causes of cognitive impairment. NeuraCeq should be used in conjunction with a clinical evaluation. A negative scan indicates sparse or no plaques, which is not consistent with a diagnosis of AD. For the limitations in the interpretation of a positive scan, please refer to the SmPC.

Important Safety Information

NeuraCeq can be used for the imaging of beta-amyloid neuritic plaque density in the brain. NeuraCeq cannot be used to diagnose Alzheimer's disease and it cannot predict a patient's predisposition for beta-amyloid plaque development in the future. NeuraCeq images should only be interpreted by readers trained in the interpretation of PET images with florbetaben (18F). Following training, image reading errors (including false positive or false negative interpretation of NeuraCeq images) may still occur. Additional interpretation errors may occur due to image noise, atrophy with a thinned cortical ribbon, or image blurs.

Administration of NeuraCeq, as with other radiopharmaceuticals, results in a low amount of ionizing radiation exposure. Safety precautions should be taken to ensure healthcare providers and patients do not receive unintentional radiation exposure from NeuraCeq.

Most Common Adverse Events

The most common side effects observed in clinical trials were injection site reaction and injection site pain.

About Piramal Imaging

Piramal Imaging, 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.

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