

Press Release

Piramal Imaging Announces EU Approval of NeuraCeq $^{\text{TM}}$ (florbetaben 18F) * for PET Imaging of Beta-Amyloid Neuritic Plaque Density in the Brain

Berlin/Boston; February 24, 2014 – Piramal Imaging announced today that NeuraCeq[™] has received marketing authorization from the European Commission.

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.

With this authorization, NeuraCeq™ will soon be available to provide valuable information that may give physicians more confidence in their clinical assessment and help them provide more personalized patient management as a negative scan may rule out AD as a cause of a patient's cognitive decline.

"With the prevalence of dementia predicted to grow dramatically in the coming decades, the global communities are mobilizing to understand the pathology and progression of Alzheimer's disease and other forms of cognitive impairment," said Dr. Ludger Dinkelborg, Director of the Board, Piramal Imaging. "The approval of NeuraCeq™ in Europe will give healthcare providers a new tool to aid in the diagnostic assessment of AD and other causes of cognitive impairment. Our goal from here is to get NeuraCeq™ into the hands of physicians later this year so they can help ensure timely and accurate assessments for patients."

"Our belief in the diagnostic importance of molecular imaging led us to make a strategic investment in the Bayer research pipeline and create the Piramal Imaging business," said Dr. Swati Piramal, Vice Chairperson, Piramal Enterprises, Ltd. "In just two years, we are already at the approval milestone in Europe for the first of our compounds setting us up to provide physicians and patients with valuable information about cognitive impairment and decline. Early diagnosis can be powerful knowledge for certain clinicians and families and may lead to faster action and better care – all of which we value to our core at Piramal Enterprises."

Data from the pivotal phase III autopsy study showed that PET imaging with NeuraCeq™ detects neuritic beta-amyloid in the brains of living subjects. The visual subject-level PET reading proposed for routine clinical practice compared to histopathology for the first 31 brains demonstrated 100 percent sensitivity and 86 percent specificity. In a post-hoc analysis in a larger population with 74 autopsied subjects, the sensitivity of the visual assessment was 98 percent and specificity was 89 percent.

NeuraCeq[™] will be available in select European countries in the second and third quarters of 2014.



Piramal Imaging has partnered with IBA Molecular for manufacturing and distribution of NeuraCeq[™] upon EU approval. IBA Molecular owns and operates a network of 49 PET isotope facilities worldwide, a network that is unique in both size and scope.

About NeuraCeq™ (florbetaben 18F)

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 $^{\text{TM}}$ can be used for the imaging of beta-amyloid neuritic plaque density in the brain. NeuraCeq $^{\text{TM}}$ 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 $^{\text{TM}}$ 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 $^{\text{TM}}$ 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 $^{\text{TM}}$, 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 $^{\text{TM}}$.

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.

About Piramal Enterprises, Ltd.

Piramal Enterprises (PEL) is one of India's largest diversified companies, with a presence in pharmaceuticals, financial services and healthcare information management sectors. PEL



had consolidated revenues of over \$650 million in FY2013. In the pharmaceutical space, PEL is one of the leading custom manufacturing players globally, has presence in the global critical care segment with a portfolio of inhalation and injectable anesthetics and its OTC business is ranked no. 7 in India. PEL is also engaged in drug discovery and research, and has a strong pipeline of development products. In the financial services space, PEL has a real estate focused PE fund – Indiareit, and a NBFC that is focused on lending to the real estate and education sectors. PEL's healthcare information management business, Decision Resources Group, is a leading provider of information-based services to the healthcare industry.

*NeuraCeq™ (florbetaben 18F) is an investigational PET amyloid imaging agent currently under review by the U.S. Food and Drug Administration.

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