

Press Release

## CHMP Recommends EU Approval of Piramal Imaging's NeuraCeq™ (Florbetaben 18F)\* for PET Imaging of Neuritic Beta-Amyloid Plaques in the Brain

**Berlin/Boston/Mumbai, December 20, 2013** – Piramal Imaging announced today the European Union's Committee for Medicinal Products for Human Use (CHMP) recommended approval of NeuraCeq™ (florbetaben 18F). The CHMP's recommendation will now be referred to the European Commission, for approval in the European Union (EU).

NeuraCeq™ is a radiopharmaceutical indicated for Positron Emission Tomography (PET) imaging of neuritic beta-amyloid 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.

"This recommendation marks a major milestone for Piramal Imaging in our commitment to assist in the diagnosis of Alzheimer's disease and the development of novel tracers for PET imaging," said Dr. Ludger Dinkelborg, Director of the Board, Piramal Imaging SA. "This is a key step towards making this innovative type of imaging more accessible to healthcare providers and patients across Europe."

Earlier this month, G8 health ministers held a dementia summit in London to discuss the challenges associated with this "major disease burden" that will likely affect one of every three people during their lifetimes. Despite its prevalence, the root cause of dementia is often misdiagnosed. As a result, a patient may not receive valuable treatments, or—if a patient does not have dementia—receive unnecessary and costly treatments that demonstrate no benefit. Following the summit, the G8 participants issued a communiqué that asked members to commit to "making timely diagnosis and early intervention feasible, affordable and cost effective."

"Alzheimer's disease is a growing epidemic, with recent data suggesting more than six million people in Europe and 36 million people worldwide are living with Alzheimer's," said Dr. Swati Piramal, Vice Chairperson, Piramal Enterprises Ltd. "When Piramal Enterprises acquired Bayer HealthCare's molecular-imaging pipeline in 2012, we were excited about the potential for NeuraCeq™ as an adjunct to other diagnostic evaluations for dementia. It arms physicians with additional data to help reduce misdiagnosis of Alzheimer's disease and may have the potential to aid in earlier diagnosis and intervention. We look forward to hearing the European Commission's final decision."

The CHMP's positive opinion was based on data from the pivotal phase III autopsy study, which 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.

It is important to note, that a positive Neuraceq™ scan does not establish a diagnosis of Alzheimer's disease or other cognitive disorder. Additionally, the safety and effectiveness of Neuraceq™ have not been established for predicting the development of dementia or other neurologic conditions or monitoring responses to therapies.

Piramal Imaging has partnered with IBA Molecular for manufacturing and distribution of NeuraCeq™ upon EU approval. IBA Molecular owns and operates a network of 54 PET isotope facilities worldwide, a network that is unique in both size and scope.

#### **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 <http://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 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 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.

#### **About IBA Molecular**

IBA Molecular is a global group of companies that develops, manufactures and distributes radiopharmaceutical products and supporting services used in molecular imaging. IBA Molecular has engineered a strong and unique product portfolio and pipeline of diagnostic and therapeutic tracers aimed at advancing the global movement towards personalized medicine and making molecular imaging/therapy a major discipline in healthcare. The company also provides educational, technical and marketing support to medical specialists worldwide to help them respond better to patient needs. For more information, please visit <http://www.ibamolecular.com> or contact IBA Molecular North America, Inc., 21000 Atlantic Boulevard, Suite 730, Dulles, Virginia 20166.

\*NeuraCeq™ (florbetaben 18F) is an investigational PET amyloid imaging agent currently under review by the U.S. Food and Drug Administration and recommended for approval in the European Union by the CHMP.

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