

Press Release

## FDA Approves Piramal Imaging's Neuraceq™ (florbetaben F18 injection) for PET Imaging of Beta-Amyloid Neuritic Plaques in the Brain

**Berlin/Boston, March 20, 2014** – Piramal Imaging today announced that the U.S. Food and Drug Administration (FDA) has approved Neuraceq™. This approval comes only four weeks after receiving marketing authorization for Neuraceq™ from the European Commission.

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.

There are an estimated 7.7 million new cases of dementia each year worldwide.<sup>1</sup> Alzheimer's disease accounts for 60-80% of all dementia diagnoses.<sup>2</sup> However, a clinical diagnosis of probable AD is incorrect upon post-mortem histological investigation in 10-30% of cases.<sup>3</sup>

The Centers for Medicare & Medicaid Services (CMS) has declared it will cover a beta-amyloid PET scan for patients under Coverage with Evidence Development (CED) programs. The objective of these programs is to assess the impact of beta-amyloid scans on improving patient outcomes or advancing patient treatment options.

"Alzheimer's disease or any form of cognitive impairment is a daunting diagnosis," said Dr. Ludger Dinkelborg, Director of the Board, Piramal Imaging. "For the patients and caregivers, the concern centers around understanding what the future holds. For physicians, the challenge is properly assessing the patient and determining the best care path."

"The FDA's approval of Neuraceq™ is a significant milestone for Piramal Imaging and demonstrates our dedication to advancing innovation in molecular imaging globally," said Dr. Swati Piramal, Vice Chairperson, Piramal Enterprises, Ltd. "The rising prevalence of Alzheimer's disease and cognitive impairment is being felt individually and collectively around the world. Our goal as a company is to usher in a new era of imaging that helps paint clearer pictures of the physiology of such conditions and helps improve patient outcomes."

The FDA approval of Neuraceq™ is based on safety data from 872 patients who participated in global clinical trials as well as three studies that examined images from adults with a range of cognitive function, including 205 end-of-life patients who had agreed to participate in a post-mortem brain donation program. Images were analyzed from 82 subjects with post-mortem confirmation of the presence or absence of beta-amyloid neuritic plaques. Correlation of the visual PET interpretation with histopathology in these 82 brains demonstrated that Neuraceq™ accurately detects moderate to frequent beta-amyloid neuritic plaques in the brain and is a useful tool to estimate the density of these plaques in life.

Piramal Imaging has partnered with IBA Molecular for manufacturing and distribution of Neuraceq™. 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 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**

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](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 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.

1. WHO. Dementia: A public health priority; 2012 2. Alzheimer's Association. *Alzheimer Dement*. 2013;9 3. American Psychiatric Association. *Practice guideline for the treatment of patients with Alzheimer's disease and other dementias*. Second edition. 2007.  
<http://psychiatryonline.org/content.aspx?bookid=28&sectionid=1679489#152139> (accessed 20 Dec 2011);

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