

Press Release

## RESEARCH ON PIRAMAL IMAGING'S NEURACEQ™ (florbetaben F18 injection) TAKES CENTER STAGE AT SNMMI

**Berlin/Boston/Mumbai, June 10, 2014** – Piramal Imaging today released details from research presented at the Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging (SNMMI), currently underway at St. Louis Convention Center in St. Louis, Mo.

Yesterday, during the AD II: Advanced Approaches Session, research findings relating to the development and approval of Neuraceq™ (florbetaben F18 injection) took center stage. Three different presentations in the session revealed findings from discrete studies exploring the efficacy and application of Neuraceq.

The sessions were just part of the robust line-up of Piramal Imaging data at the show. A total of 12 SNMMI Scientific Paper presentations and posters are featuring research relating to Piramal Imaging's product and pipeline.

"The strength of our partnership with the research community has been on display throughout SNMMI," said Dr. Andrew Stephens, Chief Medical Officer, Piramal Imaging. "It is this partnership that allows us to push the innovation envelope for Piramal and Molecular Imaging as a field. The research presented here will be the basis for product advancements for years to come."

In yesterday's talks, there was a specific focus on science that improved the understanding of the value of beta-amyloid imaging as a tool for assessing patients with cognitive impairment. As independent researchers, these clinical experts discussed uses of beta-amyloid agents that are not completely reflected in the label approved by the FDA. Nevertheless, they highlight the exciting emerging science underlying this new diagnostic tool. The three presentations highlighted below, each led by different key researchers, offered new insight into the clinical value and application for Neuraceq:

- In a presentation titled "A negative florbetaben PET scan reliably excludes AD pathology as confirmed by histopathology," Dr. John Seibyl of Molecular NeuroImaging, New Haven, focused on the very high negative predictive value of Neuraceq scans.
- In his presentation "Efficacy and reliability of the visual assessment of 18F-florbetaben PET scans in the detection of beta-amyloid neuritic plaques in the brain," Dr. Osama Sabri of the University of Leipzig, Germany, revealed that the robustness of the visual scan assessment method developed for Neuraceq results in high sensitivity and specificity even in challenging scans and restrictive reading conditions.
- Finally, Dr. Henryk Barthel of the University of Leipzig, Germany, presented "Early  $\beta$ -amyloid PET images are a valuable surrogate biomarker of neuronal injury in dementia patients," which showed that a single tracer injection may provide information on both neuronal integrity (as FDG) and beta-amyloid deposition.

### **About Neuraceq**

Neuraceq was approved in the US and EU earlier this year. 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 positives) 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.

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