

Press Release

## First US Commercial Neuraceq™ Scan for Beta-Amyloid Plaque Imaging Performed at WVU Healthcare

**Boston/West Virginia, August 12, 2014** Piramal Imaging today announced that WVU Healthcare in West Virginia, is the first center in the United States to perform commercial scans using Neuraceq. Neuraceq became available for commercial use on August 1, marking the first time patients are able to receive Neuraceq scans in the United States outside of research studies.

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 was approved by the FDA earlier this year. Neuraceq scans will be available commercially for referring physicians and patients across the U.S. in the coming weeks and months.

"At WVU Healthcare, we are making history as the first center in the U.S. to offer patients access to beta-amyloid imaging with florbetaben without enrolling in a research trial." said Dr. Gary D. Marano, Medical Director of Nuclear Medicine and PET/CT. "For us as clinicians, it's a new diagnostic option to offer patients and referring physicians in cases of cognitive decline and concerns for Alzheimer's disease."

"As a company dedicated to innovation in molecular imaging, it was important to deliver Neuraceq into hands of trained dementia experts as soon as possible to start advancing treatment options and improving patient outcomes." said Friedrich Gause, Chief Operating Officer, Piramal Imaging "We view this as an important milestone but just the beginning of our work to bring beta-amyloid imaging to the U.S. patient population."

### **About Neuraceq**

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).

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