New Research on Neuraceq™ (florbetaben F18 injection) Imaging to be Presented at Annual Alzheimer’s Association International Conference

New Data Results Provide Research Community with Better Understanding of Alzheimer’s Disease Diagnosis & Pathology

BOSTON, July 22, 2016 – Piramal Imaging today announces the presentation of 11 studies demonstrating the increasing interest in Neuraceq™ (florbetaben F18 injection), the company’s diagnostic imaging agent, in Positron Emission Tomography (PET) imaging. The study results collectively add to the growing body of research for the improved understanding of Alzheimer’s disease pathology and validate the clinical utility of identifying beta-amyloid (Aβ) plaques in the brain with florbetaben PET imaging to facilitate earlier and more accurate diagnosis of Alzheimer’s disease in patients with cognitive impairment. The study results will be presented at the annual Alzheimer’s Association International Conference (AAIC) from July 22-28, 2016 at the Metro Toronto Convention Center in Toronto, Canada.

“We are looking forward to sharing the latest analyses on Neuraceq in the fight to improve the diagnosis and management of Alzheimer’s disease at the AAIC annual meeting,” said Andrew Stephens, M.D., Ph.D., Chief Medical Officer of Piramal Imaging. “We hope that the research shared during this meeting will provide fresh insights into an emerging technology that aims to detect the onset of Alzheimer’s disease early and help physicians, patients and caregivers better plan for the future.”

The presentations will cover research on reference regions, longitudinal datasets, and various ongoing clinical studies, respectively, in using Neuraceq-PET imaging to detect the presence or absence of beta-amyloid plaques in the brain.

“The data presented at AAIC enhances our understanding on the use of Neuraceq as a radiopharmaceutical for detecting beta-amyloid plaques in Alzheimer’s disease,” said Dr. Stephens. “Together, these data presentations provide important insights into the diagnostic value of Neuraceq, quantification aspects and ongoing clinical trials in distinct study populations.”
Selected florbetaben presentations at AAIC include the following:

- **Date and Time:** Sunday, July 24, 9:30 AM - 10:30 AM  
  **Location:** Hall D/E  
  **Abstract #:** P1-096  
  **Title:** Impact of Recruitment Methods in Subjective Cognitive Decline  
  **Scheduled Presenter:** Carla Abdelnour, M.D., Fundació ACE, Barcelona Alzheimer Treatment & Research Center, Barcelona, Spain

- **Date and Time:** Sunday, July 24, 12:00 PM - 1:00 PM  
  **Location:** Hall D/E  
  **Abstract #:** P1-321  
  **Title:** White Matter Microstructure Disruption Could be an Early Phenomenon in the Pathophysiology of Preclinical Alzheimer’s Disease. Fundació ACE Healthy Brain Initiative  
  **Scheduled Presenter:** Octavio Rodriguez-Gomez, M.D., Fundacio ACE, Barcelona Alzheimer Treatment & Research Center, Barcelona, Spain

- **Date and Time:** Sunday, July 24, 12:00 PM - 1:00 PM*  
  **Location:** Hall D/E  
  **Abstract #:** P1-297  
  **Title:** The Diagnostic Value of Amyloid PET in an Unselected Cohort of Memory Clinic Patients  
  **Scheduled Presenter:** Arno de Wilde, M.D., Alzheimer Center, Department of Neurology, VU University Medical Center, Amsterdam, Netherlands  
  *additional presentation at the Alzheimer’s Imaging Consortium on Saturday, July 23, 12:15 PM - 2:00 PM, Abstract IC-P-003, Hall E

- **Date and Time:** Monday, July 25, 9:30 AM - 10:30 AM  
  **Location:** Hall D/E  
  **Abstract #:** P2-020  
  **Title:** Targeting Preclinical Stages of Alzheimer’s Disease: A Clinical Trial to Assess the Efficacy of Curcumin Using Brain Biomarkers  
  **Scheduled Presenter:** Kathryn Goozee, MCN, NP, School of Psychiatry and Clinical Neurosciences, University of Western Australia, Perth, Australia
• **Date and Time:** Monday, July 25, 12:00 PM - 1:00 PM*
  **Location:** Hall D/E
  **Abstract #:** P2-271
  **Title:** Optimal Reference Region to Measure Longitudinal Amyloid-Beta Change with 18F-Florbetaben PET
  **Scheduled Presenter:** Susan De Santi, Ph.D., VP Medical Affairs North America and Asia Pacific, Piramal Imaging
  *additional presentation at the Alzheimer's Imaging Consortium on Saturday, July 23, 12:15 PM - 2:00 PM, Abstract IC-P-003, Hall E

• **Date and Time:** Monday, July 25, 12:00 PM - 1:00 PM*
  **Location:** Hall D/E
  **Abstract #:** P2-141
  **Title:** Fundació ACE Healthy Brain Initiative: A Study of Cognition and Biomarkers in Individuals with Subjective Cognitive Decline
  **Scheduled Presenter:** Octavio Rodriguez-Gomez, M.D., Fundacio ACE, Barcelona Alzheimer Treatment & Research Center, Barcelona, Spain

• **Date and Time:** Monday, July 25, 12:00 PM - 1:00 PM*
  **Location:** Hall D/E
  **Abstract #:** P2-183
  **Title:** An Amyloid PET Positive Subject with HIV and Dementia
  **Scheduled Presenter:** Raymond Scott Turner, M.D., Ph.D., Georgetown University, Washington, DC, USA

• **Date and Time:** Monday, July 25, 12:00 PM - 1:00 PM
  **Location:** Hall D/E
  **Abstract #:** P2-228
  **Title:** In Vivo Assessment of Markers of Alzheimer’s Disease Pathology in Vietnam War Veterans with Chronic Post-Traumatic Stress Disorder
  **Scheduled Presenter:** Tia L. Cummins, The Florey Institute of Neuroscience and Mental Health, Melbourne, Australia

• **Date and Time:** Monday, July 25, 3:15 PM - 3:30 PM*
  **Location:** Hall D/E
  **Abstract #:** O2-04-06
  **Title:** Extraversion Is Associated with Lower Amyloid Deposition in Cognitively Normal Elderly
  **Scheduled Presenter:** Hwamee Oh, Ph.D., Columbia University, New York, NY, USA
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 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 www.piramal.com/imaging.

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