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Piramal Imaging to Present Research on PET Imaging and Influence of Beta-Amyloid Plaques in the Brain at Annual Alzheimer’s Association International Conference

Study Results Provide Research Community with Better Understanding of Alzheimer’s Disease

BOSTON, July 15, 2015 – Piramal Imaging today announces the presentation of nine studies regarding Neuraceq™ (florbetaben F18 injection), the company’s diagnostic imaging agent, in positron emission tomography (PET) imaging. The study results will be presented at the annual Alzheimer’s Association International Conference (AAIC) and Amyloid Imaging Consortium (AIC) from July 18-23, 2015 at the Walter E. Washington Convention Center in Washington, D.C. The studies collectively add to the growing body of research about the clinical utility of identifying beta-amyloid (Aβ) plaques in the brain.

“The AAIC annual meeting is a unique gathering of researchers, physicians, advocates, patients and caregivers, all of whom are here to share information and learn about the latest research advances in the fight to improve the diagnosis and management of Alzheimer’s disease,” said Andrew Stephens, M.D., Chief Medical Officer of Piramal Imaging. “Piramal researchers are proud to be among the many esteemed scientists who are striving to improve the way physicians diagnose and manage this increasingly prevalent and devastating disease.”

Among the abstracts accepted, two studies will be presented during oral sessions on amyloid imaging on Wednesday, July 22, 2015. In addition to the nine studies being presented at AAIC, industry experts from Piramal Imaging will discuss clinical cases and research studies in a symposium entitled, “The CPR of Amyloid Imaging: Clinical Assessment, Image Processing and Reimbursement,” on Tuesday, July 21, 2015 from 6:30 to 9:30 p.m. ET at the Renaissance DC Downtown Hotel. To reserve a ticket for the non-CME symposium, please click here.

Notable florbetaben datasets at AAIC include the following oral presentations:

- Date and Time: Wednesday, July 22, 2015, 4:15 p.m. to 5:45 p.m. ET
- Location: Ballroom B
- Abstract #: O4-08-03
- Title: Do Cerebellar Plaques Influence 18F-Florbetaben Amyloid PET Scan Quantification?
- Scheduled Presenter: Ana Catafau, M.D., Ph.D., VP of Clinical Research and
Development, Neurosciences, Piramal Imaging

- **Date and Time:** Wednesday, July 22, 2015, 4:15 p.m. to 5:45 p.m. ET  
  **Location:** Ballroom B  
  **Abstract #:** O4-08-02  
  **Title:** Impact of Morphologically Distinct Amyloid b Deposits on 18F-Florbetaben PET Scans  
  **Scheduled Presenter:** James Leverenz, M.D., Clinic Physician, Cleveland Clinic Lou Ruvo Center for Brain Health

Notable florbetaben poster presentations at AIC and AAIC include:

- **Date and Time:** Saturday, July 18, 2015, 12:15 p.m. to 2:15 p.m. ET  
  **Location:** AIC Exhibit Hall E  
  **Poster #:** IC-P-001  
  **Title:** Do Cerebellar Plaques Influence 18F-Florbetaben Amyloid PET Scan Quantification?  
  **Lead Author:** Ana Catafau, M.D., Ph.D., VP of Clinical Research and Development, Neurosciences, Piramal Imaging

- **Date and Time:** Saturday, July 18, 2015, 12:15 p.m. to 2:15 p.m. ET  
  **Location:** AIC Exhibit Hall E  
  **Poster #:** IC-P-002  
  **Title:** Impact of Morphologically Distinct Amyloid b (Ab) Deposits on 18F-Florbetaben (FBB) PET Scans  
  **Lead Author:** James Leverenz, M.D., Clinic Physician, Cleveland Clinic Lou Ruvo Center for Brain Health

- **Date and Time:** Saturday, July 18, 2015, 12:15 p.m. to 2:15 p.m. ET  
  **Location:** AIC Exhibit Hall E  
  **Poster #:** IC-P-072  
  **Title:** Aβ-Related Functional Alteration in a Frontoparietal Control Network in Cognitively Normal Elderly  
  **Lead Author:** Hwamee Oh, Ph.D., Assistant Professor of Neuropsychology, Department of Neurology, Taub Institute for Research on Alzheimer’s Disease and the Aging Brain, Columbia University Medical Center

- **Date and Time:** Saturday, July 18, 2015, 12:15 p.m. to 2:15 p.m. ET  
  **Location:** AIC Exhibit Hall E  
  **Poster #:** IC-P-016  
  **Title:** Amyloid Imaging in Therapeutic Trials: The Quest for the Optimal Reference Region  
  **Lead Author:** Victor Villemagne, M.D., Senior Research Fellow, Neurology Research, Austin Health

- **Date and Time:** Monday, July 20, 2015, 9:30 a.m. to 4:15 a.m. ET  
  **Location:** AIC Exhibit Hall D  
  **Poster #:** IC-P2-164
Title: Aβ-Related Functional Alteration in a Frontoparietal Control Network in Cognitively Normal Elderly

Lead Author: Hwamee Oh, Ph.D., Assistant Professor of Neuropsychology, Department of Neurology, Taub Institute for Research on Alzheimer’s Disease and the Aging Brain, Columbia University Medical Center

• Date and Time: Tuesday, July 21, 2015, 9:30 a.m. to 4:15 p.m. ET
• Location: AIC Exhibit Hall D
• Poster #: IC-P3-142

Title: Alzheimer’s Biomarkers in Daily Practice (ABIDE): Study Design

Lead Author: Arno De Wilde, M.D., VU University Medical Center Amsterdam

• Date and Time: Wednesday, July 22, 2015, 9:30 a.m. to 4:15 p.m. ET
• Location: AIC Exhibit Hall E
• Poster #: IC-P4-178

Title: A Study of Optimal SUVR Cutpoints and Reference Regions for Florbetaben PET

Lead Author: Gregory Klein, Ph.D., Director of Medical Imaging, BioClinica

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:
  o Predicting development of dementia or other neurologic conditions;
  o 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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