Piramal Imaging to Present New Research in PET Imaging at Society of Nuclear Medicine and Molecular Imaging 2017 Annual Meeting

Research Presented During Scientific Sessions Provides Insights into Clinical Applications and Utility of Amyloid Imaging and New Data on Investigational Imaging Agents

Denver, June 10, 2017 – Piramal Imaging today announced new research on positron emission tomography (PET) imaging tracers to be presented at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2017 annual meeting in Denver, CO. Five abstracts on the approved diagnostic imaging agent florbetaben F18 present new analyses and provide more detailed information on the clinical applications and impact of amyloid-PET imaging. Five additional abstracts present promising clinical data of several investigational PET imaging compounds.

“Previous studies have revealed that PET imaging with florbetaben provides high diagnostic accuracy in identifying beta-amyloid plaques in the brain,” said Andrew Stephens, chief medical officer, Piramal Imaging. “New datasets build on this research, focusing on the clinical contributions of florbetaben PET.”

Among the florbetaben abstracts accepted, there will be four oral presentations during the scientific session “Amyloid Imaging Goes Clinical” on Tuesday, June 13. Those comprise new analyses about the scanning start time for florbetaben, the florbetaben Centiloid transformation, and about the dual biomarker information that can be obtained from a single florbetaben injection using early-phase and late imaging time points. Furthermore, new evidence will be presented on the incremental impact of florbetaben PET imaging on the diagnosis and management of patients with suspected Alzheimer’s disease (AD) in the context of the existing healthcare framework in France, where lumbar puncture is recommended.

New pre-clinical and clinical data of the research program on the investigational tau PET-imaging tracer PI-2620, run in collaboration with AC Immune SA, will be presented in two contributions. In AD subjects, PI-2620 showed a clear pattern of high uptake particularly in the lateral temporal and frontal lobes, consistent with the expected tau pathology. In patients with Progressive Supranuclear Palsy strong PI-2620 uptake was noted in substantia nigra and globus pallidus of subjects. In contrast, PI-2620 did not exhibit an increased tracer uptake in choroid plexus, striatum, amygdala or other regions of non-demented control subjects as seen with several other tau tracers. “We are excited that the excellent preclinical profile translates into the clinic. We are looking forward to advancing PI-2620 into larger clinical trials”, said Dr. Ludger Dinkelborg, Director of the Board of Piramal Imaging.
Piramal Imaging continues to advance its knowledge about its oncology and cardiovascular imaging compounds. Besides updates on $^{68}$Ga-RM2 in recurrent prostate cancer and $^{18}$F-FSPG, the first clinical data from the investigational thrombus imaging agent $^{18}$F-GP1 will be presented. This new agent binds to glycoprotein IIb/IIIa receptors on activated platelets and is currently being evaluated in patients with arterial or venous thromboembolism in a collaboration with the ASAN Medical Center in Seoul (South Korea). In an interim analysis $^{18}$F-GP1 PET identified thromboembolic foci in all 15 patients. Additional lesions were observed that were not detected with standard imaging.

Notable datasets with Piramal Imaging compounds include the following SNMMI presentations:

<table>
<thead>
<tr>
<th>Format</th>
<th>Schedule</th>
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<tr>
<td>1</td>
<td>Oral 6/13/2017 3:10–3:20 PM</td>
<td>How flexible is $^{18}$F-florbetaben (FBB) amyloid PET imaging regarding scan start time? H. Barthel</td>
<td>Room 702/704/706 Session SS66: Amyloid Imaging Goes Clinical Abstract No. 555</td>
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<td>3</td>
<td>Oral 6/13/2017 3:50–4:00 PM</td>
<td>Application of the Centiloid transformation to $^{18}$F-florbetaben C.C. Rowe</td>
<td>Room 702/704/706 Session SS66: Amyloid Imaging Goes Clinical Abstract No. 559</td>
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<td>5</td>
<td>Poster 6/13/2017 2:45–4:15 PM</td>
<td>PET imaging of amyloid beta retention in sleep deprivation G.-J. Wang</td>
<td>Hall C No. 1253 Session MTA II: Neurology Posters Abstract No. 1253</td>
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## Compound: Tau PI-2620

| 6 | Oral  | 6/13/2017 5:25–5:35 PM | Initial clinical PET studies with the novel Tau agent $^{18}$F PI-2620 in Alzheimer's disease and controls  
**J.P. Seibyl** | Room 702/704/706  
Session SS74: Novel Clinical Applications in Tauopathy and Epilepsy  
Abstract No. 630 |

| 7 | Poster | 6/11/2017 7:00–8:30 PM | Characterization of the novel PET Tracer PI-2620 for the assessment of Tau pathology in Alzheimer’s disease and other tauopathies  
**A. Mueller** | Hall C No 847  
Session SPECIAL MTA: Probes for Neuroimaging Posters  
Abstract No. 847 |

## Compound: GP1

| 8 | Oral  | 6/13/2017 10:00 AM - 10:10AM | Exploratory clinical trial of $^{18}$F-GP1 for imaging arterial or venous thromboembolism using positron emission tomography: interim analysis of an open-label, single center study  
**S. Jin** | Room 710/712  
Session SS53: Nuclear Cardiology: New Tracers and Methods  
Abstract No. 438 |

## Compound: FSPG

| 9 | Oral  | 6/11/2017 3:20–3:30 PM | Pilot study of $^{18}$F-FSPG vs $^{18}$F-FDG PET imaging for response assessment in cancer  
**S.Y. Park** | Room 605  
Session SS16: Other Tumors Abstract No. 118 |

## Compound: RM2

| 10 | Oral  | 6/14/2017 8:50–9:00 AM | Detection of Recurrent Prostate Cancer Using $^{68}$Ga-RM2 PET/MRI in Patients with Negative Conventional Imaging  
**C. Harrison** | Room 710/712  
Session SS83: Prostate II: Biochemical Recurrence Abstract No. 711 |
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 1090 Neuraceq™ administrations were injection/application site erythema (1.7%), injection site irritation (1.1%), and injection site pain (3.4%).
About the tau research collaboration
PI-2620 was discovered in a research collaboration between Piramal Imaging and AC Immune, a Swiss-based clinical stage biopharmaceutical company focused on neurodegenerative diseases. Piramal Imaging obtained the exclusive, world-wide license for research, development and commercialization of all tau PET tracers generated within the discovery program. First-in-man clinical studies were performed at Molecular Neuroimaging LLC, a division of Invicro LLC, New Haven, Connecticut.

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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