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Piramal Imaging Applauds Interim Results and Reiterates Support of IDEAS Trial in Mild Cognitive Impairment (MCI) and Atypical Dementia

Trial Led by Alzheimer's Association and American College of Radiology Evaluating Impact of Brain Amyloid PET Imaging on Patient Management and Health Outcomes

LONDON, July 19, 2017 – Piramal Imaging joins its industry partners in applauding interim results from the ongoing "Imaging Dementia – Evidence for Amyloid Scanning" (IDEAS) clinical trial, in which pre-defined patients are undergoing positron emission tomography (PET) scanning of beta-amyloid deposits in their brains, a core feature of Alzheimer's disease (AD). Piramal Imaging's FDA-approved diagnostic radiotracer for brain beta-amyloid detection, Neuraceq™ (florbetaben F18 injection), is one of three radiotracers used in the IDEAS trial. The company is also providing funding and support for the study, which is evaluating the impact of brain amyloid PET imaging on medical management and health outcomes in enrolled patients with mild cognitive impairment (MCI) or atypical dementia.

In a presentation at the 2017 Alzheimer's Association International Conference (AAIC 2017), the Principal Investigator Gil Rabinovici, MD, of the Memory and Aging Center, University of California, San Francisco, reported findings from the first 3,979 IDEAS trial participants for whom case report forms were completed both before and 90 days after PET scanning. The investigators observed changes in medical management in 67.8% of patients with MCI, of whom 47.8% experienced changes in their AD drug regimens, 36.0% had other drugs changed, and 23.9% underwent changes in counseling.

"The interim results from the IDEAS Study suggest we are well on track to see beneficial results at the level we originally envisioned, and perhaps even greater, regarding changes in medical management based on having a brain amyloid PET scan," commented James Hendrix, PhD, Alzheimer's Association Director of Global Science Initiatives. "We look forward to working with the study scientists to report the final results."

Launched in 2016, the IDEAS trial is being led by the Alzheimer's Association, and managed by the American College of Radiology (ACR) and American College of Radiology Imaging Network (ACRIN). The trial is being conducted at roughly 200 sites throughout the United States, and will enroll more than 18,000 Medicare beneficiaries age 65 years or older with MCI or atypical dementia who meet published Appropriate Use Criteria (AUC) for clinical amyloid PET scanning.

"We salute the IDEAS investigators and the participating patients for providing such a strong indication of the value of beta-amyloid imaging, particularly in terms of influencing patient management," said Andrew Stephens, M.D., Ph.D., Chief Medical Officer of Piramal Imaging. "The early results validate our ongoing support of the IDEAS trial, which reflects our commitment to enhancing understanding of the role of beta-amyloid imaging in individuals with cognitive impairment or dementia. We look forward to receiving full results from the IDEAS trial, which we hope will lead to improved health outcomes in the management of Alzheimer's disease and related disorders."

AD is typically diagnosed after a person with a cognitive impairment undergoes an extensive clinical examination, which typically includes family and medical history, physical neurological and psychiatric examinations, laboratory tests, and imaging procedures such as computed tomography (CT) or magnetic resonance imaging (MRI) scans. However, today many patients with dementia symptoms can be misdiagnosed and a typical patient experiences symptoms for two years and visits an average of two to three doctors before receiving a clinical diagnosis. A definitive diagnosis of AD can only be made after death, based on autopsy findings of beta-amyloid plaques and neurofibrillary tangles in the brain. Today the combination of clinical diagnosis and a beta-amyloid biomarker assessment improves the diagnostic accuracy while the patient is still alive.

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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