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**Piramal Imaging is Proud to Support Major New Research Study Assessing the Value of PET Scans in Alzheimer’s Disease and Dementia Diagnosis**

*Alzheimer’s Association and American College of Radiology Lead IDEAS Trial to Inform Medicare Coverage of Brain Amyloid Imaging*

**BOSTON, April 22, 2015** – Piramal Imaging is proud to announce it will provide funding and support, along with other industry partners, for a major clinical study titled, “Imaging Dementia – Evidence for Amyloid Scanning” (IDEAS). The trial is designed to evaluate the impact of positron emission tomography (PET) scanning of beta-amyloid deposits in the diagnosis of Alzheimer’s disease (AD) in a defined patient population. Piramal Imaging’s FDA-approved diagnostic radiotracer for brain beta-amyloid detection, Neuraceq™ (florbetaben F18 injection), will be one of three radiotracers used in the study.

“Our support of the IDEAS trial demonstrates our commitment to better understanding the role of beta-amyloid imaging for patients with cognitive impairment or dementia,” said Andrew Stephens, M.D., Ph.D., Chief Medical Officer of Piramal Imaging. “We are motivated by the prospect that information from studies such as this will help U.S. physicians, dealing with cognitive impairment on a day-to-day basis, accurately and confidently differentiate Alzheimer’s disease from other etiologies.”

The IDEAS initiative, which is led by the Alzheimer’s Association and managed by the American College of Radiology (ACR) and American College of Radiology Imaging Network (ACRIN), will enroll a total of 18,488 eligible Medicare beneficiaries age 65 and older at roughly 200 sites throughout the United States over the next two years. The study will assess the impact of brain beta-amyloid PET imaging on a variety of patient outcome measures. The study protocol received approval with requirements by the Centers for Medicare & Medicaid Services (CMS). Participating providers will be reimbursed for the PET scans under the CMS Coverage with Evidence Development (CED) policy that requires research study participation as a condition of Medicare payment.

“We’re confident the IDEAS study will add to the growing body of clinical evidence and patient reported outcomes to support a positive review by CMS for reimbursement of amyloid imaging – a critical pathway to providing patients with appropriate access to beta-amyloid PET imaging with Neuraceq™,” said Friedrich Gause, Chief Operating Officer of Piramal Imaging. “Piramal is honored to be part of this

major initiative and looks forward to the results of the study, which we believe will show the benefit of imaging to patients and their families affected by this devastating disease.”

Alzheimer's disease 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 Alzheimer's disease 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**

This medicinal product is for diagnostic use only.

Neuraceq is a radiopharmaceutical indicated for Positron Emission Tomography (PET) imaging of beta-amyloid neuritic plaque density in the brains of adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) and other causes of cognitive impairment. Neuraceq should be used in conjunction with a clinical evaluation. A negative scan indicates sparse or no neuritic plaques, which is not consistent with a diagnosis of AD. For the limitations in the interpretation of a positive scan, please refer to the US package insert.

#### **Important Safety Information**

Neuraceq cannot be used to diagnose Alzheimer's disease and it cannot predict a patient's predisposition for beta-amyloid neuritic plaque development in the future. Neuraceq images should only be interpreted by readers trained in the interpretation of PET images with florbetaben (18F injection). Following training, image-reading errors (including false positive or false negative interpretation of Neuraceq images) may still occur. Additional interpretation errors may occur due to image noise, brain atrophy with a thinned cortical ribbon, or image blurs.

Administration of Neuraceq, as with other radiopharmaceuticals, results in a low amount of ionizing radiation exposure. Safety precautions should be taken to ensure healthcare providers and patients do not receive unintentional radiation exposure from Neuraceq.

#### **Most Common Adverse Events**

The most common side effects observed in clinical trials were injection site reaction and injection site pain.

#### **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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