Press Release

PIRAMAL IMAGING PROVIDES COMMENTS IN RESPONSE TO THE CENTERS FOR MEDICARE AND MEDICAID SERVICES' (CMS') PROPOSED COVERAGE DECISION FOR BETA-AMYLOID POSITRON EMISSION TOMOGRAPHY (PET)

Boston, August 19, 2013 – Piramal Imaging announced today that the company has submitted a detailed response to CMS regarding the draft decision to limit Medicare coverage of beta-amyloid PET imaging in dementia and neurodegenerative disease.[1] Piramal Imaging's response, originally submitted on Monday, July 29, 2013, has been posted on CMS' website as part of the public comment process, which was open through August 2, 2013. As of August 8, 2013, CMS' website indicated more than 200 people had posted a response. Although the final decision is not expected before October 2, 2013, Piramal Imaging strongly encourages the public to continue to submit evidence to CMS showing why beta-amyloid imaging is a medically necessary diagnostic tool for appropriate Medicare populations by sending it to CAGInquiries@cms.hhs.gov.

In Piramal Imaging's letter to CMS signed by Dr. Andrew Stephens, Vice President of Clinical Research and Development, the company expressed concerns that the CMS draft coverage decision is overly restrictive and, if finalized in its current form, would place an undue burden on physicians, patients, and caregivers by delaying the definitive diagnosis of certain types of dementia and neurodegenerative diseases, including Alzheimer's disease (AD).

The letter addresses four specific areas of concern and offers recommendations for consideration which are highlighted below:

1. Agreement with CMS's determination that there is a clear benefit to rule out AD in precisely defined patient populations where a differential diagnosis is clinically difficult and to distinguish from other forms of dementia, e.g. frontotemporal dementia. Piramal Imaging has requested Medicare coverage for these patients without requiring enrollment in a clinical trial.

    Clinical presentation of early onset AD can be difficult to distinguish from other forms of dementia and can be present with many atypical features which obfuscate the diagnosis.

    The results of beta-amyloid PET imaging thus can help the physician with the differential diagnosis of the patient, leading to identification of other appropriate treatments and tests to administer. It can help the physician to determine whether further testing is needed and to select pharmacologic and non-pharmacologic options for the patient's treatable conditions, , and it may enable the patient to forgo potentially futile testing and treatment.

    Furthermore, Piramal Imaging believes, that there is a patient population for which beta-amyloid PET imaging meets the "reasonable and necessary" threshold for the diagnosis of disease: those patients meeting the Appropriate Use Criteria (AUC)

developed by the Society of Nuclear Medicine and Molecular Imaging (SNMMI) and the Alzheimer's Association.

2. CMS should establish a clear standard of the level of evidence required to expand coverage.

   CMS should approve any clinical trials that are likely to expeditiously answer one or several of the three proposed research questions without onerous restrictions. In particular, CMS should allow for a variety of practical clinical trial designs and relevant endpoints providing they address and help answer all or at least one of CMS' research questions.

3. CMS should state in its final decision memo that once a clinical trial meets endpoints as agreed upon by CMS, they will expand Medicare coverage in a corresponding manner without any undue delay.

   The decision to expand coverage based on the results of a successful clinical trial should not unnecessarily delay the National Coverage Determination process. Medicare beneficiaries should not lose access to diagnostic technologies that have demonstrated clinical benefits in patient outcomes.

4. CMS should not require a postmortem autopsy as an endpoint for any CMS-approved clinical trial.

   Several pivotal autopsy studies demonstrate amyloid imaging agents bind to beta-amyloid in the brain therefore, further biomarker studies are redundant. According to the Agency for Healthcare Research and Quality (AHRQ) Clinical Research Standard no. 3, "the research study does not unjustifiably duplicate existing studies." Therefore, additional post-mortem autopsy studies would not fulfill the above AHRQ standard. In addition, many Medicare beneficiaries may understandably be very uncomfortable or unwilling to agree to such a requirement to undergo a diagnostic imaging scan.

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. Piramal Imaging's ^{18}F labeled beta-amyloid PET tracer, florbetaben is currently being reviewed by the Food and Drug Administration (FDA) and European Medicines Agency (EMA) for use in the visual detection of beta-amyloid in the brains of adults with cognitive impairment who are being evaluated for Alzheimer's disease (AD) and other causes of cognitive decline. For more information please go to http://imaging.piramalenterprises.com.

[1] Centers for Medicare & Medicaid Services. Proposed decision memo for beta amyloid positron emission tomography in dementia and neurodegenerative disease (CAG-00431N). http://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=265&NcaName=Beta+Amyloid+Positron+Emission+Tomography+in+Dementia+and+Neurodegenerative+Disease&CoverageSelection=National&KeyWord=beta-amyloid&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAACAAAAA%3d%3d&. Published July 3, 2013. Accessed August 8, 2013.

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