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21 March 2014 | News | By BioSpectrum Bureau

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Piramal Imaging announced that the US Food and Drug Administration (FDA) has approved Neuraceq.

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.

There are an estimated 7.7 million new cases of dementia each year worldwide. Alzheimer's disease accounts for 60-80% of all dementia diagnoses. However, a clinical diagnosis of probable AD is incorrect upon post-mortem histological investigation in 10-30% of cases.³

The Centers for Medicare & Medicaid Services (CMS) has declared it will cover a beta-amyloid PET scan for patients under Coverage with Evidence Development (CED) programs. The objective of these programs is to assess the impact of beta-amyloid scans on improving patient outcomes or advancing patient treatment options.

"Alzheimer's disease or any form of cognitive impairment is a daunting diagnosis," said Dr Ludger Dinkelborg, director of the board, Piramal Imaging. "For the patients and caregivers, the concern centers around understanding what the future holds. For physicians, the challenge is properly assessing the patient and determining the best care path."

"The FDA's approval of Neuraceq is a significant milestone for Piramal Imaging and demonstrates our dedication to advancing innovation in molecular imaging globally," said Dr. Swati Piramal, vice chairperson, Piramal Enterprises, Ltd. "The rising prevalence of Alzheimer's disease and cognitive impairment is being felt individually and collectively around the world. Our goal as a company is to usher in a new era of imaging that helps paint clearer pictures of the physiology of such conditions and help improve patient outcomes."

The FDA approval of Neuraceq is based on safety data from 872 patients who participated in global clinical trials as well as three studies that examined images from adults with a range of cognitive function, including 205 end-of-life patients who had agreed to participate in a post-mortem brain donation program. Images were analyzed from 82 subjects with post-mortem confirmation of the presence or absence of beta-amyloid neuritic plaques. Correlation of the visual PET interpretation with histopathology in these 82 brains demonstrated that Neuraceq accurately detects moderate to frequent beta-amyloid neuritic plaques in the brain and is a useful tool to estimate the density of these plaques in life.

Piramal Imaging has partnered with IBA Molecular for manufacturing and distribution of Neuraceq . IBA Molecular owns and operates a network of 49 PET isotope facilities worldwide, a network that is unique in both size and scope.