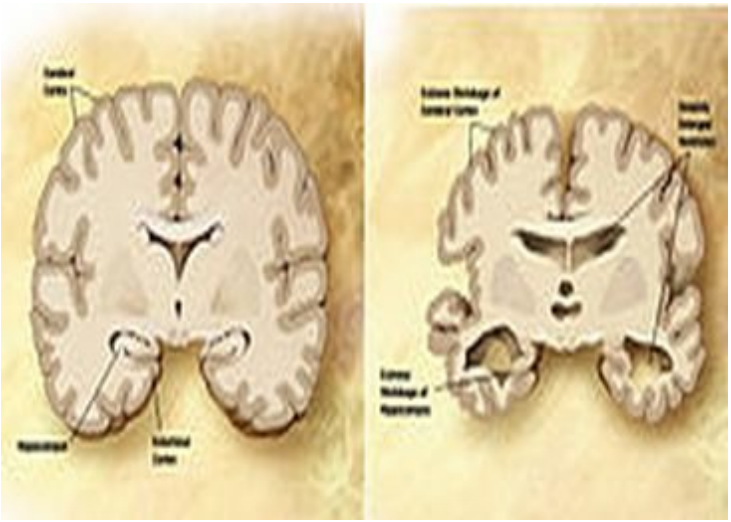
BioSpectrum the business of Bio & Health Sciences

FDA, EMA accept Piramal Imaging's applications for [18F] florbetaben

27 March 2013 | News | By BioSpectrum Bureau

FDA, EMA accept Piramal Imaging's applications for [18F] florbetaben



Piramal Imaging SA, a division of Piramal Enterprises, announced that the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have accepted its applications for review of the investigational PET amyloid imaging agent [18F] florbetaben. A New Drug Application (NDA) was submitted to the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application to the EMA for [18F] florbetaben use in the visual detection of beta-amyloid in the brains of adults with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline. [18F] florbetaben binds to beta-amyloid plaques in the human brain, a hallmark characteristic in Alzheimer's disease.

The submission of [18F] florbetaben is based on the results of a broad clinical program including a pivotal multi-center Phase III trial. This was the first study of a direct comparison between in-vivo PET imaging of the brain using [18F] florbetaben and the post-mortem analysis of brain tissue. The study was performed to confirm that [18F] florbetaben binds to beta-amyloid in the brain at the regional level and is diagnostically useful on the subject to exclude Alzheimer's disease. The presence of beta-amyloid in histopathological sections taken from the brains of deceased subjects was directly matched to [18F] florbetaben uptake in the identical regions of interest. The visual assessment procedure proposed for routine clinical practice demonstrated 100% sensitivity, 92% specificity, and excellent inter-reader agreement (kappa = 0.88). In addition, a subsequent study looked across 461 images from Phase I, II, and III studies to validate that the visual assessment method, taught by an electronic tool, is reliable (kappa = 0.87).

"The acceptance for review of [18F] florbetaben marks an important milestone in our clinical research on Alzheimer's disease. The addition of [18F] florbetaben PET imaging to the current clinical evaluation of people suffering from cognitive decline may help to increase the diagnostic confidence of physicians addressing a significant medical need by providing earlier and more robust information to people and their caregivers. We also see a potential for our product to contribute in the future to the early detection of Alzheimer's disease and facilitate specific treatment decisions," said Dr. Ludger Dinkelborg, Director of the Board, Piramal Imaging SA. Mr Renaud Dehareng, Chief Executive Officer of IBA Molecular, also welcomed the acceptance for review of [18F] florbetaben.

In 2012 IBA Molecular and Piramal Imaging signed an agreement to the effect that IBA Molecular would manufacture and distribute [18F] florbetaben upon regulatory approval in both the United States and Europe. The company owns and operates a network of 54 PET isotope facilities worldwide, a network that is unique in both size and scope.

Mr Dehareng said, "We believe our network of PET isotope facilities is well positioned to maximize patient access to [18F] florbetaben and is strongly committed to providing our customers and their patients with the best quality product and service possible."

Today, Alzheimer's disease is usually diagnosed after a person with a cognitive impairment undergoes an extensive clinical examination which typically includes family and medical history, physical and neurological examinations, laboratory tests, and imaging procedures such as computed tomography (CT) and magnetic resonance imaging (MRI) scans. Still, a definitive diagnosis of Alzheimer's disease can only be made after death where an autopsy can reveal the presence of beta-amyloid plaques and neurofibrillary tangles in the brain. However, post-mortem studies looking for accumulations of beta-amyloid in the brain have shown that 10 to 30 percent of diagnoses based on clinical examinations are incorrect. [18F] florbetaben is being studied to determine its potential ability to detect beta-amyloid plaques in living subjects with cognitive impairment.