

Press Release

Piramal Imaging announces the acceptance for review of [^{18}F] florbetaben by the FDA and EMA for the visual detection of beta-amyloid in Alzheimer's disease

Boston/Mumbai, March 21, 2013 – Piramal Imaging SA, a division of Piramal Enterprises, today 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 [^{18}F] 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 [^{18}F] 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. [^{18}F] florbetaben binds to beta-amyloid plaques in the human brain, a hallmark characteristic in Alzheimer's disease.

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. [^{18}F] florbetaben is being studied to determine its potential ability to detect beta-amyloid plaques in living subjects with cognitive impairment.

The submission of [^{18}F] 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 [^{18}F] florbetaben and the post-mortem analysis of brain tissue. The study was performed to confirm that [^{18}F] 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 [^{18}F] 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. 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. 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."

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Notes to the editors:

About florbetaben

[¹⁸F] florbetaben is an ¹⁸F-labeled tracer for use in positron emission tomography (PET) which specifically binds to beta-amyloid deposits in the brain, a key pathological hallmark in Alzheimer's disease. A Phase III trial presented for the first time at the annual meeting of the American Academy of Neurology in 2012 showed that PET imaging with [¹⁸F] florbetaben detects beta-amyloid in the

brains of living subjects. The visual assessment procedure proposed for routine clinical practice demonstrated 100% sensitivity and 92% specificity.

About Alzheimer's disease

Alzheimer's disease is a progressive neurodegenerative disease which primarily affects people over the age of 60 and is the most common cause of dementia. In 2009 estimates suggested that more than 36 million people worldwide were suffering from Alzheimer's. This figure could exceed 115 million by 2050. At present there is no cure for the disease, although treatments which may help with certain symptoms, combined with the right services and support, can improve the quality of life for the millions of people living with Alzheimer's.

About Piramal Enterprises Ltd.

Piramal Enterprises is one of India's largest diversified companies with operations in pharmaceuticals, financial services and information management. Piramal Enterprises generated consolidated revenues of \$500 million in the 2012 financial year. In the pharmaceuticals field, Piramal Enterprises is one of the leading custom manufacturing players in the world and operates in the global critical-care segment with a portfolio of inhalation and injectable anesthetics. Its OTC business is ranked number 7 in India. PEL is also involved in drug discovery & research and has strong pipeline of development products. In the financial services field, PEL has a real-estate-focused PE fund called Indiareit, and an NBFC that focuses on lending to the real-estate and education sector. Recently, PEL also entered the global information-management industry by acquiring the US-based company Decision Resources Group. PEL acquired the global rights to a molecular-imaging research and development portfolio from Bayer AG. The portfolio includes the rights to [¹⁸F] florbetaben, a highly specialized molecule used in PET imaging to detect beta-amyloid in the brain, a widely recognized marker for Alzheimer's disease.

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 <http://piramalenterprises.com>.

About IBA Molecular

IBA Molecular is a global group of companies that develops, manufactures and distributes radiopharmaceutical products and supporting services used in molecular imaging. IBA Molecular has engineered a strong and unique product portfolio and pipeline of diagnostic and therapeutic tracers aimed at advancing the global movement towards personalized medicine and making molecular imaging/therapy a major discipline in healthcare. The company also provides educational, technical and marketing support to medical specialists worldwide to help them respond better to patient needs. For more information, please visit <http://www.ibamolecular.com> or contact IBA Molecular North America, Inc., 21000 Atlantic Boulevard, Suite 730, Dulles, Virginia 20166.