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Piramal Alzheimer's detector gets FDA, EMA nod

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Singapore: The US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have accepted Piramal Imaging's applications for review of the investigational PET amyloid imaging agent [18F] florbetaben. A New Drug Application (NDA) was submitted to the FDA and a Marketing Authorization Application to the EMA for [18F] florbetabenuse.

Florbetabenuse can be used in the visual detection of beta-amyloid in the brains of adultswith cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline. It 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] florbetabenandthe 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'sdisease.

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 percent sensitivity, 92 percent 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).

Dr Ludger Dinkelborg, director, Piramal Imaging SA, said that, "The acceptance for reviewof [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."