BioSpectrum the business of Bio & Health Sciences ASIA EDITION

EMA recommends nod for first radiopharmaceutical

22 October 2012 | News | By BioSpectrum Bureau

EMA recommends approval of first radiopharmaceutical

Singapore: The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended marketing authorisation for Amyvid (florbetapir 18F) as a diagnostic agent in patients who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline.

Amyvid is a radiopharmaceutical agent used in positron emission tomography (PET) imaging in the brains of adults. It can highlight amyloid protein plaques in the brain, and assist in the diagnosis of AD.

Alzheimer's disease is the most common cause of dementia in the elderly, affecting up to 5.1 million people in the European Union. Accurate diagnosis of AD has been hampered to date by the lack of diagnostic tests. The current gold standard for confirming a clinical diagnosis of AD is post-mortem autopsy.

PET imaging using Amyvid can provide useful information on neuritic plaque density in the brains of patients who are being tested for cognitive decline. Following intravenous injection, the radioactive agent Amyvid binds to Î²-amyloid in the brain. Î²-amyloid protein is present in the brains of people with AD and other cognitive disorders.

Importantly, a negative Amyvid PET scan can rule out the presence of AD, and is expected to reduce the frequency of false positive diagnosis. However, a positive Amyvid scan is consistent with, but does not independently establish, the diagnosis of AD since Î²-amyloid neuritic plaque deposition may also be present in the brain of asymptomatic elderly and some neurodegenerative dementias, including Parkinson's disease dementia and Lewy body dementia.