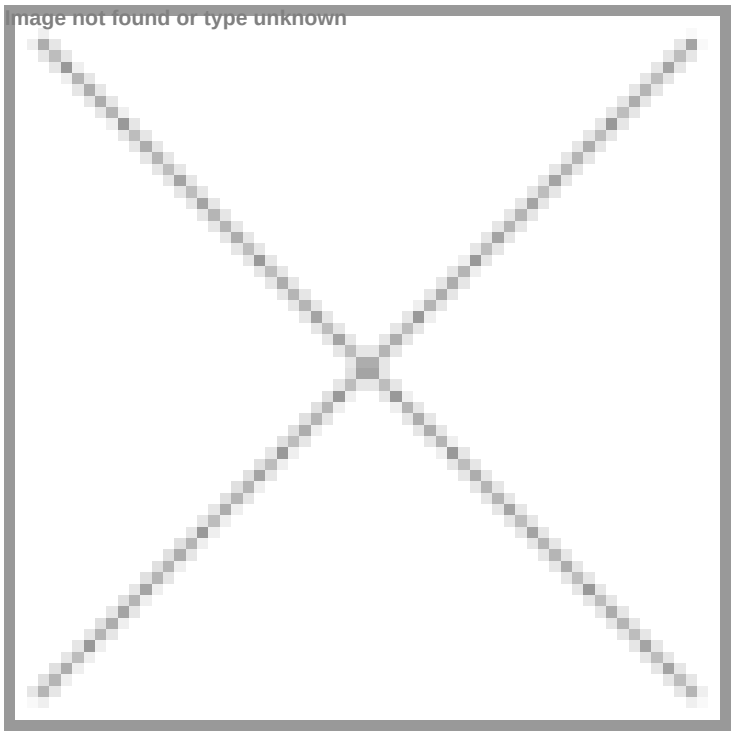
BioSpectrum the business of Bio & Health Sciences

CHMP Recommends EU Approval of Piramal Imaging's NeuraCeq

30 November -0001 | News | By BioSpectrum Bureau

CHMP Recommends EU Approval of Piramal Imaging's NeuraCeq



Piramal Imaging announced today the European Union's Committee for Medicinal Products for Human Use (CHMP) recommended approval of NeuraCeqTM (florbetaben 18F). The CHMP's recommendation will now be referred to the European Commission, for approval in the European Union (EU).

NeuraCeqTM is a radiopharmaceutical indicated for Positron Emission Tomography (PET) imaging of neuritic beta-amyloid plaque densityin the brains of adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) and other causes of cognitive impairment.

"This recommendation marks a major milestone for Piramal Imaging in our commitment to assist in the diagnosis of Alzheimer's disease and the development of novel tracers for PET imaging," said Dr. Ludger Dinkelborg, Director of the Board, Piramal Imaging SA. "This is a key step towards making this innovative type of imaging more accessible to healthcare providers and patients across Europe."

Earlier this month, G8 health ministers held a dementia summit in London to discuss the challenges associated with this "major disease burden" that will likely affect one of every three people during their lifetimes. Despite its prevalence, the root cause of dementia is often misdiagnosed. As a result, a patient may not receive valuable treatments, or-if a patient does not have dementia-receive unnecessary and costlytreatments that demonstrate no benefit. Following the summit, the G8 participants issued a communiquÃ© that asked members to commit to "making timely diagnosis and early intervention

feasible, affordable and cost effective."

"Alzheimer's disease is a growing epidemic, with recent data suggesting more than six million people in Europe and 36 million people worldwide are living with Alzheimer's," said Dr. Swati Piramal, Vice Chairperson, Piramal Enterprises Ltd. "When Piramal Enterprises acquired Bayer HealthCare's molecular-imaging pipeline in 2012, we were excited about the potential for NeuraCeqTM as an adjunct to other diagnostic evaluations for dementia. It arms physicians with additional data to help reduce misdiagnosis of Alzheimer's diseaseand may have the potential to aid in earlier diagnosis and intervention. We look forward to hearing the European Commission's final decision."

The CHMP's positive opinion was based on data from the pivotal phase III autopsy study, which showed that PET imaging with NeuraCeqTMdetects neuritic beta-amyloid in the brains of living subjects. The visual subject-level PET reading proposed for routine clinical practice compared to histopathology for the first 31 brains demonstrated 100 percent sensitivity and 86 percent specificity.In a post-hoc analysis in a larger population with 74 autopsied subjects, the sensitivity of the visual assessment was 98 percent and specificity was 89 percent.

It is important to note, that a positive NeuraceqTM scan does not establish a diagnosis of Alzheimer's disease or other cognitive disorder. Additionally, the safety and effectiveness of NeuraceqTM have not been established for predicting the development of dementia or other neurologic conditions or monitoring responses to therapies.