



News Release for Medical Media

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Bayer Schering Pharma Starts Phase III Trial with Florbetaben

Development of PET tracer florbetaben for beta-amyloid imaging in patients with Alzheimer's disease is progressing as planned

Newbury, UK/Chicago, November 30, 2009 – The development of Bayer Schering Pharma's florbetaben, to support the diagnosis of Alzheimer's disease, is progressing well. On the occasion of the 95th Scientific Assembly and Annual Meeting of the Radiological Society of North America (RSNA), the company announced the enrolment of the first patients in an international clinical Phase III trial to evaluate the efficacy and safety of florbetaben (BAY 94-9172) PET imaging in the detection of beta-amyloid deposition in the brain. The trial will include both subjects with and without manifest dementia (e.g. Alzheimer's disease [AD]). In the previous Phase II trial, florbetaben has demonstrated its potential to detect beta-amyloid deposition in the brain as a pathological hallmark of disease in AD patients.

“Currently, there is no diagnostic tool on the market to facilitate the *in vivo* diagnosis of the various dementia types including Alzheimer's disease,” said Dr. Thomas Balzer, Head of Global Clinical Development Diagnostic Imaging at Bayer Schering Pharma. This Phase III study could prove that florbetaben can be used as a new tool to detect beta-amyloid depositions in the brain *in vivo*. The ability to produce images of beta-amyloid depositions has the potential to provide an improved and earlier diagnosis of this devastating disease, as well as eventually allowing a more specific treatment to be initiated earlier.”

Phase III Trial Design

The pivotal Phase III trial is an open-label, multi-centre, non-randomised single dose study to assess the safety and to determine the sensitivity and specificity of the visual and quantitative assessment of regional tracer uptake of florbetaben in the brain using PET

imaging. Approximately 400 individuals are expected to be enrolled in this study. The florbetaben uptake pattern will be visually assessed by independent, nuclear medicine physicians blinded to the clinical diagnosis and all other clinical data. The images will be compared for the presence or absence of cerebral beta-amyloid relative to corresponding histo-pathological specimens. Both volunteers without dementia and patients with dementia will be included, therefore enrolling subjects with either a high probability of cerebral beta-amyloid deposition (e.g. subjects with AD) or a low probability of cerebral beta-amyloid deposition (e.g. non-demented volunteers).

The primary and secondary objectives of the trial are the evaluation of the sensitivity and specificity of the visual assessment of regional tracer uptake in the florbetaben PET images compared to histological verification as well as the quantitative assessment of regional tracer uptake. The primary completion of the study is anticipated for 2011. However, due to histopathology examinations the study is not anticipated to be completed before 2014.

Phase II Trial Results¹

The global Phase II, open-label, non randomised, multi-centre study aimed to evaluate the efficacy and safety of florbetaben PET *in vivo* imaging in the detection/exclusion of cerebral beta-amyloid plaques in patients with mild-to-moderate, probable AD (older than 55 years of age) compared with age-matched healthy volunteers. A total of 18 study centres in four countries (Australia, Germany, USA and Switzerland) screened 213 individuals of whom 150 individuals were imaged with florbetaben receiving a single intravenous injection of the tracer. Reliable, high-quality images were obtained across multiple centres and camera types.

The results of this study showed PET images with a high specificity of more than 90 percent (more than 90 percent of the healthy volunteers had a negative florbetaben scan) in the relevant brain regions. The results also showed a sensitivity of approximately 80 percent indicated by the clinical diagnosis, meaning that about 80 percent of the clinically suspected Alzheimer patients had positive florbetaben scans indicating the presence of beta-amyloid plaques. This is in line with the results of studies comparing the clinical diagnosis with the definite post-mortem histopathological diagnosis.

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Twenty-nine adverse events (AEs) were reported in 24 of the participants (16 percent) and only five of them were deemed to be related to florbetaben. Most of the AEs were injection site changes. Most AEs in the trial were resolved during the study period. Bayer Schering Pharma has decided to extend this study and is currently recruiting patients in USA, Germany, Japan, Australia and Switzerland.

About Florbetaben (BAY 94-9172)

Florbetaben is currently not licensed or available. It is an unlicensed ^{18}F -labeled PET tracer that specifically binds to deposition of beta-amyloid. These depositions (plaques) consist of proteins that accumulate in the brain and are a pathological hallmark of Alzheimer's disease. As the aggregation of the beta-amyloid protein in the brain is also a key target for new therapeutic treatments under development, florbetaben might also be able to support the development of these new treatment approaches. A Phase II study showed that patients with clinical diagnosis of Alzheimer's disease could be differentiated from age-matched healthy volunteers on the basis of florbetaben uptake pattern in the brain. The results of the Phase II study were presented at the International Conference on Alzheimer's diseases (ICAD) in Vienna, Austria in July 2009.

About Alzheimer's Disease

Alzheimer's disease is a devastating neuro-degenerative disease and the most common cause of dementia. Most cases of Alzheimer's disease affect people over the age of 60. It is a progressive disease that can lead to premature death.

In 2006, estimates suggested that more than 26 million people worldwide were suffering from Alzheimer's disease. By 2050, this number could reach more than 100 million. At present there is no cure for Alzheimer's disease, but treatments for symptoms, combined with the right services and support, can make life better for the millions of people living with Alzheimer's.

About Bayer Schering Pharma

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging,

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General Medicine, Haematology & Neurology, Oncology and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialised markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of patients' lives.

Further information can be found at www.bayerscheringpharma.co.uk

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References:

¹: Data on file, July 2009

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