



Fact Sheet

Bayer Schering Pharma Development Projects

Business Unit: Diagnostic Imaging

Development candidate [¹⁸F]AV1/ZK – First option for molecular diagnosis of Alzheimer’s disease before clinical manifestation of the disease

- Specific binding to amyloid plaques in the brain
- Proof of Mechanism study completed successfully
- Start of a Phase II study planned for 2008

Status: June 2007

<p>Project description</p> <p>[¹⁸F]AV1/ZK (BAY94-9172) is a novel radiopharmaceutical with the potential to enable early diagnosis of Alzheimer’s disease to be made for the first time at the molecular level. The fluorine-labelled substance binds to beta-amyloid, the main constituent of amyloid plaques which form in the brain of Alzheimer patients. The distribution of the radionuclide is visualized using the positron emission tomography (PET) imaging procedure.</p> <p>Data from an initial clinical study with [¹⁸F]AV1/ZK provided evidence that the innovative molecular diagnostic procedure is capable of differentiating between Alzheimer patients and healthy elderly people (Proof of Mechanism). In contrast to healthy subjects, [¹⁸F]AV1/ZK PET images exhibited a high signal strength in Alzheimer patients,</p>	<p>At a glance</p>
	<p>Name of the active substance</p> <p>[¹⁸F]AV1/ZK (BAY94-9172)</p>
	<p>Type of substance</p> <p>¹⁸F-labelled low-molecular substance belonging to the chemical class of the stilbenes</p>

<p>especially in those areas of the brain where amyloid plaques are known to be found. The positive results of the study were presented in June 2007 at the annual conference of the Society of Nuclear Medicine in Washington DC, USA.</p>	<p>Targeted Indication Early diagnosis of Alzheimer's disease</p>
<p>Bayer Schering Pharma has exercised its rights to license [¹⁸F]AV1/ZK from Avid Radiopharmaceuticals. The start of a Phase II study is planned for 2008.</p>	<p>Administration form Intravenous injection</p>
<p>The medical background In the USA alone, an estimated 4.5 million people suffer from Alzheimer's disease. The number has doubled since 1980 and it is expected that with the increasing ageing of the U.S. population, it will top the 12 million mark by the year 2050. Based on worldwide representative epidemiological studies, the number of individuals who suffer from dementia today is estimated at 24.3 million. Every year, there are about 4.6 million new cases in addition. The number of affected individuals doubles every 20 years, so that in the year 2040 it would be expected to be at 81.1 million. 50% to 75% of these cases are caused by Alzheimer's disease.</p>	<p>Mode of action Binding to beta-amyloid, imaging by positron emission tomography (PET)</p>
<p>With present diagnostic methods, the disease can only be diagnosed in an advanced stage; this means only when cognitive deficits are clearly evident. At present, the lack of clinical procedures for reliable diagnosis of this serious disease presents a considerable obstacle to the treatment of affected patients as well as to the development of new therapies.</p>	<p>Status</p> <ul style="list-style-type: none"> ▪ Clinical Phase I study (Proof of Mechanism) completed ▪ Start of a Phase II study planned for 2008
<p>Active substance [¹⁸F]AV1/ZK The fluorine-labelled radiopharmaceutical [¹⁸F]AV1/ZK binds directly to the amyloid plaques in the brain which are considered to be the cause of Alzheimer's disease. [¹⁸F]AV1/ZK can be used in connection with the non-invasive imaging procedures such as positron emission</p>	<p>Collaborating partner Avid Radiopharmaceuticals, Inc. Philadelphia, PA, USA</p> <p>www.avidrp.com</p>

tomography (PET). PET is based on displaying the distribution of a radioactively labelled substance in the organism. The ability of [¹⁸F]AV1/ZK to accumulate predominantly in brain structures with a high amyloid-beta burden has already been proven in initial clinical studies in humans.

Molecular imaging at Bayer Schering Pharma

Molecular imaging involves diagnostic procedures which make it possible, in particular, to identify the first precursors of diseases at the cellular and molecular level even before they manifest clinically. This is aimed at providing both earlier and more precise identification of, for example, tumors and diseases of the central nervous system. In the area of molecular imaging, Bayer Schering Pharma is pursuing promising approaches with innovative carrier molecules which bind highly specifically to certain cell structures. This leads to the development of procedures for imaging disease-specific biological processes at a molecular level. The main focus is on cancer diagnosis and the diagnostics of neurodegenerative diseases. Bayer Schering Pharma has several collaborative partnerships in the area of molecular imaging, for example with Avid Pharmaceuticals, Inc., Stanford University and Taisho Pharmaceutical Co., Ltd.

Bayer HealthCare

Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma and as Bayer HealthCare Pharmaceuticals in the US and Canada. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide.

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, Hematology/Cardiology, Oncology, Primary Care, Specialized Therapeutics and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life.

Research and Development at Bayer Schering Pharma

Bayer Schering Pharma concentrates its R&D activities on innovative treatment approaches for diseases with a high unmet medical need to improve patients' quality of life and prolong lives. In this context, Bayer Schering Pharma focuses on its core competencies and its many years of experience. Thus, Bayer Schering Pharma holds a leading position in many therapeutic fields: for example, in the treatment of hemophilia and multiple sclerosis, in contrast media and oral contraception. We are also striving for a leading position in oncology. With new approaches in cancer therapy, for cardiovascular diseases, gynaecological therapies and in molecular imaging, Bayer Schering Pharma aims to become an innovation leader in these fields. In addition, Bayer Schering Pharma further develops products already on the market in order to improve their application and/or extend their range of indications.

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Forward-looking statements

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