AC Immune and Bayer Schering Pharma collaborate in brain imaging for Alzheimer’s Disease

- Bayer’s diagnostic will be used in Phase I clinical trial of AC Immune Alzheimer’s vaccine ACI-24

Ecublens/Lausanne, Switzerland, October 8, 2009 – AC Immune SA, a leader in Alzheimer’s Disease drug development, announced today that it has entered a collaboration with Bayer Schering Pharma on the diagnostic imaging of Alzheimer’s Disease. Bayer’s novel positron emission tomography (PET) tracer florbetaben will be applied for imaging beta-Amyloid plaques in the brain of patients undergoing the Phase I clinical testing of AC Immune’s Alzheimer’s vaccine ACI-24. This is the first time this PET tracer will be tested in treated Alzheimer’s patients.

Prof. Andrea Pfeifer, CEO of AC Immune said, “This collaboration with Bayer adds further value to our Alzheimer’s vaccine ACI-24. The adoption of a diagnostic imaging substance visualizing the deposition of beta-Amyloid that is targeted by our vaccine can be an important parameter for dose selection, and will provide useful complementary data. There is a key trend in the industry to co-develop therapy guiding diagnostics alongside drugs for patients. We look forward to working with Bayer’s experts in this ground-breaking collaboration.”

“Bayer Schering Pharma has already demonstrated the potential of florbetaben to image beta-Amyloid deposition in the brain in its own phase II study,” said Dr. Thomas Balzer, Head of Global Clinical Development Therapeutic Area Diagnostic Imaging at Bayer Schering Pharma. “The cooperation with AC Immune enables the collection of valuable clinical data for florbetaben in patients treated with AC Immune’s novel therapeutic vaccine.”

High unmet medical need
Currently there is no diagnostic test on the market that can detect beta-Amyloid plaques in the brain – a pathological hallmark of Alzheimer’s disease – in patient’s lifetime. Today, the clinical diagnosis of AD is based on cognitive tests, Magnetic Resonance Imaging (MRI) and computerized tomography (CT) scans to exclude other diseases. Unfortunately, clinical diagnosis is often made too late and does not always correlate with post-mortem diagnosis. A good diagnostic assay should also help to better evaluate the effect of new treatments in clinical trials as well as correlate better with existing pathological and memory markers. A new diagnostic tool to detect beta-Amyloid in the brain in vivo might also be beneficial in detecting the disease earlier, before the symptoms are too advanced so treatment could be started earlier.
About the ACI-24 clinical trial
The trial is a Phase I/IIa, randomized, double blind, placebo controlled clinical study with the primary objective of evaluating the safety and tolerability of ACI-24 and a secondary objective of evaluating efficacy (immune response and clinical assessment) in mild to moderate AD patients. Phase I is designed to allow for the identification of the best dose of vaccine to be used further in Phase II. Three groups of patients, each receiving a different dose of ACI-24, will be observed. The study is being run in Scandinavia.

About ACI-24
ACI-24 is an active vaccine stimulating the patient's immune system to produce beta-sheet conformation-specific antibodies that prevent plaque deposition or enhance clearance of plaques. During preclinical development, the ACI-24 has shown high efficacy in vivo by memory restoration and plaque reduction. The vaccine is also characterized by a very high specificity due to generating a conformation-specific antibody response. The favourable safety profile of ACI-24 is underlined through the absence of local inflammation in relevant models as well as its T-cell independent mechanism shown in preclinical development.

About Florbetaben
Florbetaben is a PET tracer that specifically binds to beta-Amyloid plaques. These 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 conducted by Bayer 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 this study were presented in July 2009 at the International Conference on Alzheimer’s Diseases (ICAD) in Vienna, Austria. Find more information at http://www.viva.vita.bayerhealthcare.com/

About PET tracers
Radioactive positron emission tomography (PET) tracers are used in imaging tests that help find problems inside the body. These tracers give off particles that can be detected and turned into a picture to help find problems in organs or other structures. The tracer is usually given through an intravenous (IV) line placed in a vein. The tracer then travels through the body and may collect in a certain organ or area.

About AC Immune SA:
AC Immune SA is a Swiss-based biopharmaceutical company and a leader in Alzheimer’s Disease drug development. AC Immune develops innovative therapeutics with “best in class” potential against Alzheimer’s Disease and other conformational diseases along three axes: vaccines, antibodies and small molecules. The anti-Abeta antibody for passive immunization is partnered with Genentech and entered Phase I in 2008. The company continues to develop in house the small molecule ACI-91 which entered Phase II in 2008 and the vaccine ACI-24 which commenced Phase I/IIa in 2009. These three clinical programs are focused on Alzheimer’s Disease, and are backed by a rich portfolio of preclinical compounds. Our therapeutic molecules are also leveraged for Alzheimer’s Disease diagnostic and other central nervous system and non-CNS diseases, such as Glaucoma. Since its foundation in 2003, AC Immune has raised CHF 64 million from
private investors. The out-licensing agreement with Genentech was closed at the end of 2006 for a potential value of more than US$ 300 million.

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