

## **PRESS RELEASE**

### **AC Immune and Piramal Imaging announce out-licensing agreement for the development of Tau protein diagnostics in Alzheimer's disease**

- **Potential important step towards better diagnosis and clinical management of Alzheimer's disease**
- **Tau diagnostics complement AC Immune's therapeutic product pipeline**
- **Piramal Imaging initiates Tau-PET-Imaging tracer development program**
- **Significant License Agreement signals the importance of the development of Alzheimer's Tau-PET-Imaging tracers**

**Lausanne, Switzerland/Berlin, Germany and Boston, USA – May 12, 2014 –** AC Immune SA and Piramal Imaging, a division of Piramal Enterprises Ltd., announced today that they have entered into an exclusive worldwide license agreement for the research, development and commercialization of AC Immune's Tau protein positron emission tomography (PET) tracers supporting the diagnosis and clinical management of Alzheimer's disease (AD) and potential Tau-related disorders.

The formation of Tau tangles in the human brain is recognized as one of two major hallmarks of Alzheimer's disease pathology, with the other being beta-amyloid plaques. The development of the Tau tangle pathology appears to correlate well with cognitive decline, making it a potential strong target for diagnostic approaches. The availability of a Tau-PET tracer for imaging Tau tangles in the brain of patients would represent important progress towards relevant diagnostic endpoints and could be of significant value in guiding clinical trials for disease modifying AD therapeutics.

Under the terms of the agreement, AC Immune will receive an undisclosed upfront payment and is eligible for significant milestone payments on products achieving development goals in AD and other Tauopathies. Additionally, AC Immune is entitled to receive tiered royalties on net sales of products resulting from the partnership. AC Immune will work in collaboration with Piramal Imaging to efficiently advance several lead candidates through late pre-clinical radio-pharmacology development. Piramal Imaging will have global rights for clinical development, manufacturing and commercialization of a Tau-PET Tracer resulting from the collaboration. Financial details were not disclosed.

**Prof. Andrea Pfeifer, CEO of AC Immune,** said: "We are delighted to be working with Piramal Imaging as a partner of choice given their proven experience in PET tracer development, especially in the Alzheimer's field. The collaboration is an important endorsement of AC Immune's capacity to develop both diagnostic and therapeutic agents in managing this devastating disease. This move into diagnostics complements our Tau therapeutic product pipeline exemplified by the Tau antibody partnership with Genentech and the first pTau vaccine ACI-35 now in clinical development for AD.

Diagnostics is a natural strategic step for the company and is expected to generate significant and fast revenues from product sales.”

**Dr. Ludger Dinkelborg, Director of the Board of Piramal Imaging,** added: “This collaboration with AC Immune is an important next step in our mission to developing molecular imaging innovations that allow an earlier and more accurate diagnosis of Alzheimer’s disease. So far there are no approved imaging technologies to detect Tau protein in patients, presenting a challenge in AD diagnosis and the development of disease modifying treatments. We are impressed by the quality of AC Immune’s innovative Tau-PET tracer program and are looking forward to working with the team at AC Immune, who has a proven track record in effective partnerships,” and continued: “That AC Immune selected Piramal Imaging as their diagnostic imaging partner shows we are making good progress towards our goal to become Pharma companies’ partner of choice for the development of therapy guiding diagnostics in conjunction with their therapeutic drugs.”

The agreement between the two companies is based on a long-term relationship in which AC Immune has used Piramal Imaging’s beta-amyloid PET Tracer Neuraceq™ for imaging beta-amyloid plaques in the brain of patients undergoing Phase I/IIa clinical testing of AC Immune’s Alzheimer’s vaccine ACI-24.

Neuraceq™ received marketing authorization from the FDA on March 19, 2014 for PET imaging of the brain to estimate beta-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for AD and other causes of cognitive decline. Safety and effectiveness of Neuraceq™ have not been established for monitoring responses to therapies. Neuraceq™ received similar approval by the EC four weeks earlier.

#### **About the Tau-PET Imaging program**

The innovative new Tau-PET tracers were discovered by AC Immune through its proprietary Morphomer™ chemistry technology platform. These Morphomers are a novel class of ligands that specifically target pathological forms of Tau. The excellent brain uptake and their high selectivity complete their outstanding profile as PET tracers.

#### **About Tau-PET tracers**

A brain positron emission tomography (PET) scan is an imaging test of the brain involving an imaging device and an imaging agent called a PET tracer. No Tau-PET tracers have received regulatory approval for commercial distribution, which represents a huge medical need, not only in Alzheimer’s disease but also in other potential Tauopathies. Once the Tau-PET tracer is introduced to the body, it travels to the brain and binds to abnormal Tau protein structures (Tau tangles), one of the pathological hallmarks of AD. The imaging device detects the bound Tau imaging agent and creates pictures reflecting the amount and distribution of pathological Tau in the brain.

#### **About Alzheimer’s disease**

Scientists don't yet fully understand what causes Alzheimer's disease, but it has become increasingly clear that it develops because of a complex series of events that take place in the brain over a long period of time. Two proteins – Tau and beta-amyloid – are perceived as the major hallmarks of neurodegeneration: tangles and other abnormal forms of Tau protein accumulate inside the brain cells, while plaques and oligomers formed by beta-amyloid occur outside the brain cells of people with Alzheimer's disease (AD).

AD will be one of the biggest burdens of the future society showing dramatic incidence rates: every 69 seconds someone in the US develops AD, by mid-century someone will develop the disease every 33 seconds. Forty-four million people were affected with the disease worldwide in 2013. In the US AD is now the 6th leading cause of death across all ages. It was the fifth leading cause of death for those aged 65 and older. Since the incidence and prevalence of AD increase with age, the number of patients will grow dramatically with our society getting older. By 2050 we expect that patient numbers will triple to 135 million worldwide.

#### **About AC Immune**

AC Immune SA is a Swiss-based biopharmaceutical company and a leader in Alzheimer's disease drug development. AC Immune develops innovative therapeutics and diagnostics 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 (crenezumab) for passive immunization is partnered with Genentech and is in Phase II development; it has been selected for the first groundbreaking Alzheimer's prevention trial. The company pursues the clinical development of the vaccines ACI-24 and ACI-35. These three clinical programs are focused on Alzheimer's disease, and are backed by a rich portfolio of preclinical compounds. A preclinical stage anti-Tau antibody is partnered with Genentech. The company has partnered its Tau PET tracers with Piramal. The therapeutic molecules are leveraged for Alzheimer's disease diagnostic and other central nervous system and non-CNS diseases, such as Glaucoma and Down syndrome. Since its foundation in 2003, AC Immune has raised CHF 84 million from private investors. For more information please go to [www.acimmune.com](http://www.acimmune.com).

#### **About Piramal Imaging**

Piramal Imaging, a fully owned subsidiary of Piramal Enterprises, Ltd., was formed in 2012 with the acquisition of the molecular imaging research and development portfolio of Bayer Pharma AG. By developing novel PET tracers for molecular imaging, Piramal Imaging is focusing on a key field of modern medicine. Piramal Imaging strives to be a leader in the Molecular Imaging field by developing innovative products that improve early detection and characterization of chronic and life threatening diseases, leading to better therapeutic outcomes and improved quality of life. For more information please go to [www.piramal.com/imaging](http://www.piramal.com/imaging).

## Disclaimer

Piramal Imaging cautions that statements included in this press release that are not a description of historical facts are forward-looking statements that involve risks, uncertainties, assumptions and other factors which, if they do not materialize or prove correct, could cause Piramal's results to differ materially from historical results or those expressed or implied by such forward-looking statements. Such statements are based on management's beliefs as well as assumptions made by and information currently available to Piramal. The potential risks and uncertainties, many of which are beyond Piramal's control, could contribute to the uncertain nature of these statements and include, among others, risks associated with acceptance of the Piramal's products by its customers, the outcome of any clinical trial, regulatory approval of any product, development and acceptance of new products or product enhancements, operations and business interruptions or strategic changes, expansion of our networks, and the other risks and uncertainties described in Piramal's press releases and periodic filings with appropriate regulatory agencies. Piramal assumes no obligation to update any forward-looking statement to reflect events or circumstances arising after the date on which it was made.

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