AC IMMUNE PARTNER GENENTECH TO START SECOND PHASE 3 CLINICAL TRIAL FOR ALZHEIMER’S THERAPY CRENEZUMAB

- Strong commitment to potential disease-modifying therapy
- New Phase 3 CREAD2 trial to investigate 750 participants
- Current Phase 3 CREAD1 trial of 750 participants expected to read out 2020

Lausanne, Switzerland, February 28, 2017 – AC Immune SA (NASDAQ: ACIU), a Swiss-based, clinical stage biopharmaceutical company focused on neurodegenerative diseases, today announced that its partner Genentech, member of Roche group, has decided to start a second Phase 3 clinical trial of the Alzheimer’s therapy crenezumab, an anti-Abeta antibody. This new trial CREAD2 will recruit 750 patients with prodromal or mild Alzheimer’s disease. This new trial complements the current Phase 3 CREAD1 trial of 750 participants with prodromal or mild Alzheimer’s disease, expected to read out in 2020\(^1\). Trial design details of CREAD2 are not yet available but will be posted on ClinicalTrials.Gov in due course. Crenezumab was discovered by AC Immune using its SupraAntigen technology platform and out-licensed to Genentech in 2006 as a potential therapy for Alzheimer’s disease. AC Immune will not receive any milestone payments for the start of this second Phase 3 trial since the company already received a milestone payment when the CREAD1 trial started.

Prof. Andrea Pfeifer, CEO of AC Immune, commented: “We are delighted with the strong commitment of our partner Genentech to developing crenezumab as a potential disease modifying therapy for Alzheimer’s. Given the recent disappointing results of other therapies, all of us in the Alzheimer’s community need to redouble our efforts to combat one of society’s biggest challenges. We remain confident about the potential of crenezumab given it is distinct from other beta amyloid antibodies, predominantly blocking oligomers in the brain, and has a clinical development program that is using higher dosing and targeting earlier stages of Alzheimer’s disease.”

Recent data supporting Genentech decision
Important data to support the unique binding and increased dosing of crenezumab were presented by Genentech in December 2016 at the 9th Clinical Trials on Alzheimer’s disease Conference (CTAD) in San Diego, USA.

\(^1\) [www.clinicaltrials.gov](http://www.clinicaltrials.gov) Identifier NCT02670083
Genentech has developed a comprehensive drug-disease progression model which predicts, relative to the Phase 2 trials, an increased potential of the CREAD Phase 3 clinical trial in patients with prodromal-to-mild Alzheimer by using the higher dose of 60mg/kg of crenezumab.

The safety and pharmacokinetic data of the Phase 1b dose escalation study support the continued treatment of patients with crenezumab at a higher dose of 60mg/kg.

Furthermore, a paper was published in Scientific Reports on 20 December 2016 titled “Structure of crenezumab complex with Aβ shows loss of β-hairpin” (www.nature.com/articles/srep39374). This publication describes the crystal structure of crenezumab targeting the beta amyloid oligomers. There is strong scientific evidence which suggests that those oligomers are the toxic form of Abeta and may be primarily responsible for neurotoxicity when compared to monomers and fibrils of the misfolded Abeta protein. Crenezumab is shown to bind to a unique sequential, conformational epitope that only exists in the aggregated form of Abeta. This binding induces essential molecular interactions to break up and thereby solubilizes the oligomeric form of Abeta. These insights highlight crenezumab’s unique mechanism of action, particularly regarding Abeta oligomers, and provide a strong rationale for the evaluation of crenezumab as a potential AD therapy.

**About Crenezumab**

Crenezumab was discovered by AC Immune using its SupraAntigen technology platform and out-licensed to Genentech in 2006 as a potential therapy for Alzheimer’s disease. Crenezumab is a fully humanized IgG4 monoclonal antibody that binds all forms of misfolded Abeta proteins, but especially to Abeta oligomers, to prevent and break up Abeta aggregation and promote Abeta disaggregation. The IgG4 subclass has reduced the effector function, allowing microglia to clear Abeta from the brain while minimizing an inflammatory response.

Genentech is currently evaluating the clinical efficacy and safety of Crenezumab in a Phase 3 clinical trial, CREAD, in 750 participants with prodromal or mild Alzheimer’s disease, which started in Q1 2016 and is expected to read out in 2020. In addition crenezumab was chosen by an international panel of experts, including the US National Institutes of Health, for use in a first-ever prevention trial in Alzheimer’s disease in a large extended family in Colombia (API ADAD) in 2012.

**About the out-licensing agreement**

In 2006 AC Immune closed an exclusive out-licensing agreement for its anti-Abeta antibody program with Genentech, under which Genentech develops crenezumab for the treatment of Alzheimer’s disease. AC Immune received an upfront payment and milestone payments upon the start of phase 1, phase 2 and phase 3 respectively. The contract provides potential total revenues of over USD 300 million for AC Immune
through payments upon successful completion of clinical and regulatory milestones in Alzheimer's disease and additional applications. Additionally, the company is entitled to receive royalties on net sales of products resulting from this partnership.

**About Alzheimer's disease**

It is becoming increasingly clear that Alzheimer's disease 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 (Abeta) - are recognized as major hallmarks of neurodegeneration: tangles and other abnormal forms of Tau protein accumulate inside the brain cells and spread between cells, while plaques and oligomers formed by beta-amyloid occur outside the brain cells of people with AD.

AD is one of the biggest burdens of society with a dramatic and growing worldwide incidence rate of one new case every three seconds, or 9.9 million new cases of dementia each year. Since the incidence and prevalence of AD increase with age, the number of patients will grow significantly as society ages. Worldwide in 2015 there are 46.8 million people living with dementia and by 2050 it is expected that global patient numbers will triple to 131.5 million. It is estimated that the annual societal and economic cost of dementia has risen from US$ 604 billion in 2010 to US$ 818 billion in 2015. In the US, AD is now the 6th leading cause of death across all ages and is the fifth leading cause of death for those aged 65 and older.

**About AC Immune**

AC Immune is a clinical stage Swiss-based biopharmaceutical company focused on neurodegenerative diseases with four product candidates in clinical trials. The Company designs, discovers and develops therapeutic and diagnostic products intended to prevent and modify diseases caused by misfolding proteins. AC Immune’s two proprietary technology platforms create antibodies, small molecules and vaccines designed to address a broad spectrum of neurodegenerative indications, such as Alzheimer’s disease. The Company’s pipeline features seven therapeutic and three diagnostic product candidates. The most advanced of these is crenezumab, an anti-Abeta antibody in Phase 3 clinical studies that is being advanced by the collaboration partner Genentech, Inc., a member of the Roche Group. Other business partners include Biogen, Janssen Pharmaceuticals, Nestlé Institute of Health Sciences and Piramal Imaging.

**Forward looking statements**

This press release may contain statements that constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are statements other than historical fact and may include statements that address future operating, financial or business performance or AC Immune’s strategies or expectations. In some cases, you can identify these statements by forward-looking words such as “may,” “might,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “projects,” “potential,” “outlook” or “continue,” and other comparable terminology. Forward-looking
statements are based on management’s current expectations and beliefs and involve
significant risks and uncertainties that could cause actual results, developments and
business decisions to differ materially from those contemplated by these statements.
These risks and uncertainties include, but are not limited to, the timing and conduct of
clinical trials of AC Immune’s product candidates, the clinical utility of AC Immune’s
product candidates, the timing or likelihood of regulatory filings and approvals, AC
Immune’s intellectual property position and AC Immune’s financial position. These risks
and uncertainties also include those described under the captions “Risk Factors” and
“Management’s Discussion and Analysis of Financial Condition and Results of
Operations” in AC Immune’s Registration Statement on Form F-1 and other filings with
the Securities and Exchange Commission. Forward-looking statements speak only as of
the date they are made, and AC Immune does not undertake any obligation to update
them in light of new information, future developments or otherwise, except as may be
required under applicable law. All forward-looking statements are qualified in their
entirety by this cautionary statement.

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