AC Immune Reports Initiation of a Phase 2 Substudy to Increase Understanding of Disease Progression in Familial Alzheimer's Disease

June 20, 2019

Evaluates longitudinal Tau burden in Colombia Phase 2 prevention trial for autosomal dominantly inherited AD (familial AD)

LAUSANNE, Switzerland, June 20, 2019 (GLOBE NEWSWIRE) -- AC Immune SA (NASDAQ: ACIU), a Swiss-based, clinical-stage biopharmaceutical company with a broad pipeline focused on neurodegenerative diseases, today announced that Genentech, a member of the Roche Group, has initiated a substudy in the ongoing Phase 2 Alzheimer's Prevention Initiative (API) trial of AC Immune's investigational candidate, crenezumab. The substudy, which measures Tau burden using Positron Emission Tomography (PET), aims to increase the understanding of disease progression in the preclinical stage of autosomal dominantly inherited Alzheimer's disease (familial AD).

Prof. Andrea Pfeifer, CEO of AC Immune SA, commented: "Learning more about the early distribution and severity of Abeta- and Tau-related pathology in AD is imperative in developing successful Alzheimer's treatments. This new substudy will provide further evidence on the progression of familial AD by monitoring for changes in Tau burden and help examine the potential role of crenezumab as a disease-modifying agent that may prevent the onset or slow progression in people at risk of developing familial AD."

The substudy will evaluate the effect of crenezumab, an anti-Abeta antibody, on the longitudinal Tau burden in a subgroup of presymptomatic Presenilin1 (PSEN1) E280A mutation carriers and non-carriers enrolled in API, a landmark study in Colombia to slow or prevent the decline of cognitive and functional abilities in people at risk of developing familial AD. The PSEN1 E280A mutation (or Paisa mutation) is by far the most common cause of familial early onset Alzheimer's disease. Tau proteins are abundant in neurons and Tau pathology, or Tauopathy, spreads with a characteristic spatiotemporal pattern throughout the brain, coinciding with both clinical symptoms and disease progression in AD.

The API trial in Colombia, which began in 2013 and for which data are expected in the first quarter of2022, is in cognitively healthy individuals with an autosomal dominant PSEN1 E280A mutation, which puts them at high risk of developing familial AD. This study will determine whether treating people carrying this mutation with crenezumab prior to the onset of AD symptoms, will slow or prevent the decline of cognitive and functional abilities. The new substudy will further improve the understanding of how Tauopathy may be used to track disease progression, including potential efficacy in people who may respond to treatment.

Participants in the new substudy will receive up to three intravenous injections of Genentech Tau Probe 1 and will undergo a Tau PET scan after each injection. The primary outcome measure will be change over time in Tau distribution, measured at week 130 up to week 260 of the main study.

"Treating earlier and testing in homogeneous populations are two important elements in AC Immune's Roadmap to success and, both strategies are being applied in the API trial. Testing therapeutics in a homogeneous group in people carrying the PSEN1 E280A mutation earlier in the preclinical development phase, may make it possible to identify successful treatment strategies for treating this debilitating disease," added Prof. Pfeifer.

It has been reported that many leaders in the field remain convinced that beta amyloid plays an important role in the initiation of AD. It is widely believed to be possible that studies to date have not intervened early enough or during the period before patients become symptomatic. As such, there may be an opportunity for early intervention with an investigational therapy such as crenezumab.

About Crenezumab

Crenezumab was discovered by AC Immune SA. Genentech, a member of the Roche Group, and AC Immune entered into a research collaboration and license agreement on November 6, 2006. Crenezumab is an investigational, monoclonal antibody designed to preferentially bind to and promote removal of neurotoxic oligomers, a form of beta-amyloid. Crenezumab has an antibody backbone (IgG4) designed to minimize the inflammatory response in the brain, which may result in a lower risk of certain MRI (magnetic resonance imaging) abnormalities known as ARIA (Amyloid-Related Imaging Abnormalities).

About AC Immune SA

AC Immune SA is a Nasdaq-listed clinical-stage biopharmaceutical company, which aims to become a global leader in precision medicine for neurodegenerative diseases. The Company is utilizing two proprietary discovery platforms, SupraAntigen™ and Morphomer™, to design, discover and develop small molecule and biological therapeutics as well as diagnostic products intended to diagnose, prevent and modify neurodegenerative diseases caused by misfolding proteins. The Company's pipeline features nine therapeutic and three diagnostic product candidates, with five currently in clinical trials. It has collaborations with major pharmaceutical companies including Roche/Genentech, Eli Lilly and Janssen.

For further information, please contact:

US Investors
Joshua Drumm, Ph.D.
AC Immune Investor Relations
Phone: +1 646 876 5538
E-mail: joshua.drumm@acimmune.com

US Media
Katie Gallagher or Sharon Correia
LaVoieHealthScience
Phone: +1 617 792 3937
E-mail: kgallagher@lavoiehealthscience.com
scorreia@lavoiehealthscience.com

European Media
Judith Moore
AC Immune Global Communication Lead
Phone: +44 7932 053829
E-mail: judith.moore@acimmune.com

European Investors & Media
Chris Maggos
LifeSci Advisors
Phone: +41 79 367 6254
E-mail: chris@lifesciadvisors.com

Forward looking statements

This press release contains 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 those described under the captions “Item 3. Key Information – Risk Factors” and “Item 5. Operating and Financial Review and Prospects” in AC Immune’s Annual Report on Form 20-F 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.

Source: AC Immune SA