# AC Immune Initiates Ph1b/2a Study of Anti-Phospho-Tau Vaccine in Alzheimer's Disease

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**Clinically advanced vaccine, ACI-35.030, designed to reduce and to prevent the spread and development of Tau pathology**

LAUSANNE, Switzerland, Aug. 01, 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 the initiation of a Phase 1b/2a clinical trial to evaluate ACI-35.030, an anti-phospho-Tau (anti-pTau) vaccine. ACI-35.030 targets pathological Tau and is intended as a disease-modifying treatment for Alzheimer's disease (AD) and other Tauopathies.

**Prof. Andrea Pfeifer, CEO of AC Immune SA, commented**: "Pathological Tau deposits are one of the key hallmarks of AD. Their characteristic distribution within the brain coincides with clinical symptoms and disease progression. Targeting phospho-Tau is therefore a very promising approach for treating and preventing this debilitating disease and as such, it is a key part of AC Immune's *Roadmap to Successful Therapies for Neurodegenerative Diseases*."

By targeting specific pathological forms of Tau protein, immunization with anti-Tau vaccines has become an important strategy for the treatment of AD and other Tauopathies because it has the potential to prevent and reduce the development and spread of Tau pathology throughout the brain. AC Immune's two proprietary technology platforms, SupraAntigen $^{TM}$ and Morphomer$^{TM}$, have generated anti-Tau therapies and diagnostics including four in clinical development.

This Phase 1b/2a trial is a randomized, multicenter, double-blind, placebo-controlled clinical study with a primary objective to assess the safety, tolerability and immunogenicity of different doses of ACI-35.030 in patients with early AD. Secondary objectives will assess additional immunogenicity parameters, while exploratory endpoints will include notable biomarkers of progression of AD as well as clinical assessments.

AC Immune is developing ACI-35 and ACI-35.030 in collaboration with Janssen Pharmaceuticals, Inc. under a 2014 licensing agreement to develop and commercialize therapeutic anti-Tau vaccines for the treatment of AD and potentially other Tauopathies.

**About ACI-35.030**

ACI-35.030 is a potent liposomal anti-pTau active investigational vaccine designed to elicit antibodies against extracellular phosphorylated pathological Tau protein, in order to prevent and reduce the spread and development of Tau pathology within the brain.

It builds on the success of AC Immune's ACI-35 vaccine, which has demonstrated an early target-specific antibody response against pTau after the first injection in the vast majority of patients in a Phase 1b study in mild-to-moderate AD. In pre-clinical studies, ACI-35.030 has shown that it retains the excellent non-clinical safety profile and the highly specific antibody response against pathological Tau observed in ACI-35, while demonstrating an enhanced and more homogeneous antibody response with a significant, long-lasting boosting effect.

**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$^{TM}$ and Morphomer$^{TM}$, 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 Pharmaceuticals Inc.

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**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