

AC Immune's Alzheimer's Vaccine Generates Potent Anti-pTau Antibody Response in a Phase 1b/2a Study

Interim results of ACI-35.030 vaccination show high titers of antigen-specific antibodies at potentially therapeutic levels in 100% of older patients with early Alzheimer's disease

ACI-35.030 was safe and well tolerated with no safety concerns observed. Results support plans to further develop the Alzheimer's vaccine into Phase 2/3

Lausanne, Switzerland, February 11, 2021 – AC Immune SA (NASDAQ: ACIU), a Swiss-based, clinical-stage biopharmaceutical company with a broad pipeline focused on neurodegenerative diseases, today announced positive interim results from its ongoing Phase 1b/2a clinical trial evaluating its first-in-class anti-phospho-Tau (pTau) vaccine candidate ACI-35.030 for the treatment of Alzheimer's disease (AD). ACI-35.030 vaccination generated a potent antigen-specific antibody response against pTau in 100% of older patients with early AD, achieving antibody levels several orders of magnitude higher than pre-vaccination levels. No clinically relevant adverse events were observed. AC Immune and strategic partner Janssen Pharmaceuticals, Inc., believe these interim findings from the first two dosing groups support plans to advance the development of ACI-35.030 for the treatment of AD.

Immunization with anti-Tau vaccines represents a novel strategy for the treatment of AD and other neurodegenerative diseases characterized by Tau pathology. ACI-35.030 is a first-in-class vaccine candidate designed to generate a specific antibody response against pTau proteins in the brain. Anti-pTau antibodies generated by ACI-35.030 have the potential to reduce the spread and seeding of Tau pathology, which is a major hallmark of AD.

These new results provide encouraging clinical support for ACI-35.030, which employs a new vaccine formulation to achieve active immunization that significantly improves antibody responses in older patients with potentially attenuated immune systems. Notably, anti-pTau vaccination generates antibody responses with pharmacokinetic characteristics and target epitopes that differ substantially from the Company's anti-Tau monoclonal antibody semorinemab, highlighting the comprehensive and complementary nature of AC Immune's anti-Tau pipeline.

Prof. Andrea Pfeifer, CEO of AC Immune SA, commented: "These remarkable data show that ACI-35.030 is capable of generating unprecedented antibody responses against pTau in an elderly population, with very high antigen-specific titers. Importantly, it generated a much stronger antibody response compared to direct injection of exogenous antibodies. As pathological pTau is present as a precursor many years before Tau accumulation in the brain is detectable via brain imaging, such results highlight the significant promise of ACI-35.030 as an early intervention for AD, especially when combined with cutting-edge pTau diagnostics that would enable identification of people at risk of developing Tau-driven disease. We look forward to continuing to advance ACI-35.030 in our collaboration with Janssen Pharmaceuticals, Inc., as we aim to bring this potentially breakthrough vaccine to patients."

Interim data from the Phase 1b/2a study showed:

- Anti-Tau IgG response preferentially targets phosphorylated Tau in all patients;
- 100% of patients demonstrated an anti-pTau IgG response after the 1st injection for both lowest and second highest dosages;
- Very high anti-pTau IgG titers observed following injection;
- Anti-pTau IgM response was also elicited in all patients for both doses;
- ACI-35.030 was safe and well tolerated with no clinically relevant safety concerns observed to date.

The companies plan to advance to the third and highest dosing group, per the study protocol.

ACI-35.030 is derived from AC Immune's proprietary SupraAntigen™ platform, which accelerates the discovery and development of conformation specific antibodies and vaccine candidates to power successful therapeutic and diagnostic approaches. Additional clinical-stage candidates derived from this platform include ACI-24, a proprietary anti-amyloid beta (Aβ) vaccine, crenezumab, an anti-Aβ monoclonal antibody, and semorinemab, an anti-Tau monoclonal antibody, which is in Phase 2 development for the treatment of moderate AD.

AC Immune's SupraAntigen™ platform has also more recently generated conformation-specific antibodies against emerging neurodegenerative disease targets such as alpha-synuclein, TDP-43 and the NLRP3 inflammasome pathway. AC Immune's programs directed against these emerging targets are among the most advanced and comprehensive in the field.

About the Phase 1b/2a pTau AD Vaccine Trial

AC Immune's Phase 1b/2a pTau AD vaccine 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 over a 48-week treatment phase in 32 patients with early AD. Other endpoints will assess clinical and cognitive parameters as well as additional immunogenicity and safety parameters.

About ACI-35.030

ACI-35.030 is a potent liposomal anti-pTau active investigational vaccine designed to elicit antibodies against phosphorylated pathological Tau protein. It is designed to reduce and facilitate the clearance of related Tau aggregates, slowing the progression of Tau-pathology and/or treating the underlying Tauopathy.

It builds on the success of AC Immune's ACI-35 vaccine, which demonstrated an early target-specific antibody response against pTau after the first injection in the vast majority of participants in a Phase 1b study in mild-to-moderate AD. In preclinical studies, ACI-35.030 retained the excellent non-clinical safety profile and the highly specific antibody response against phosphorylated pathological Tau produced by ACI-35, while demonstrating an enhanced and more homogeneous antibody response.

AC Immune is developing the ACI-35.030 vaccine 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 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 utilizes two proprietary 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 six currently in clinical trials. It has collaborations with major pharmaceutical companies including Genentech, a member of the Roche Group, Eli Lilly and Company and Janssen Pharmaceuticals.

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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. These include: the impact of Covid-19 on our business, suppliers, patients and employees and any other impact of Covid-19. 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.