

AC Immune Advances phospho-Tau Alzheimer's Vaccine in Phase 1b/2a Study

Interim data confirm the promising safety, tolerability and Tau-specific immunogenicity observed in the previous clinical study

ACI-35.030 is a clinical stage vaccine generated with the proprietary SupraAntigen™ platform addressing proteinopathies across neurodegenerative diseases

Lausanne, Switzerland, July 16, 2020 – 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 the second highest dosing group in the Company's [Phase 1b/2a clinical trial](#) evaluating ACI-35.030 for the treatment of Alzheimer's disease (AD). The decision to advance to the higher dosing group follows encouraging interim safety, tolerability and immunogenicity results from the initial dosing group.

Immunization with anti-Tau vaccines has become an important strategy for the treatment of AD and other neurodegenerative diseases characterized by Tau pathology. ACI-35.030, which is being developed in collaboration with [Janssen Pharmaceuticals, Inc.](#), is the first AD vaccine candidate designed to generate a specific antibody response against pathologic phospho-Tau (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 throughout the brain.

Prof. Andrea Pfeifer, CEO of AC Immune SA, commented: “The fact that ACI-35.030 shows encouraging safety and immunogenicity at the lowest dose in this elderly patient population is highly meaningful and we look forward to quickly enrolling this next dosing group. Tau-targeted approaches may have a much broader therapeutic window to potentially disrupt, slow or prevent disease progression at both early and advanced disease stages. Pathological pTau occurs early in the disease process, years before accumulation of Tau deposits. Therefore, our pTau-targeting approach holds significant promise for the treatment of AD at different disease stages.”

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 over a 48-week treatment phase in patients with early AD. Other endpoints will assess clinical and cognitive parameters as well as additional immunogenicity and safety parameters.

The ACI-35.030 anti-pTau vaccine is the second vaccine under investigation generated from AC Immune's SupraAntigen™ platform, along with ACI-24, a proprietary anti-amyloid beta (Abeta) vaccine currently in Phase 1b/Phase 2 clinical development in two separate indications. The Company's pipeline is also advancing two monoclonal antibodies, semorinemab, an anti-Tau antibody in Phase 2 development and crenezumab, an anti-Abeta antibody in Phase 2 development, both partnered with Genentech/Roche.

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, in order 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 patients 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 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 Company, 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. 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.