

AC Immune Announces Expansion of Phase 1b/2a phospho-Tau Alzheimer's Vaccine Trial and Provides a Program Update

Previous interim results showing strong safety and potent immunogenicity support trial expansion and advancement of ACI-35.030 into Phase 2b/3

Alternative vaccine candidate also advances to second highest dose group based on encouraging interim results

Lausanne, Switzerland, May 17, 2021 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today announced that the Company and its strategic partner Janssen Pharmaceuticals, Inc., have expanded the ongoing Phase 1b/2a clinical trial of the Companies' first-in-class anti-phosphorylated-Tau (pTau) vaccine candidate ACI-35.030 for the treatment of Alzheimer's disease (AD). The trial expansion, which is based on [encouraging interim safety, tolerability and immunogenicity results](#) to date, specifically includes vaccination of additional AD patients at the second highest dose to support continued development of ACI-35.030 into Phase 2b/3. In parallel, the trial continues to evaluate patients in the highest dose cohort, for which the first interim results will be available in Q4 2021.

Interim results from the low and second highest dose groups of the Phase 1b/2a trial showed that ACI-35.030 vaccination generated a potent antigen-specific antibody response against pTau in 100% of older patients with early AD with no clinically relevant safety concerns observed to date. These data, as well as additional interim Phase 1b/2a results, will be presented at an upcoming medical congress.

Long-term immunization with vaccines represents a valuable strategy for treatment and potentially prevention of AD and other neurodegenerative diseases. ACI-35.030 is the first AD vaccine candidate designed to generate antibodies that specifically target pathological pTau proteins in the brain. Anti-pTau antibodies generated continually in the body by ACI-35.030 have the potential to reduce and prevent the spread and seeding of Tau pathology, which is a major hallmark of AD.

Prof. Andrea Pfeifer, CEO of AC Immune SA, commented: "Expanding the second highest dose cohort will increase the amount of immunogenicity and safety data and potentially facilitate advancement into a Phase 2b/3 trial. We look forward to presenting interim results later this year and further assessing the potential of our highly promising vaccine candidate with our collaboration partner Janssen Pharmaceuticals, Inc. In parallel, we are pleased to evaluate a second alternative pTau vaccine candidate, which may provide additional optionality for future development."

In addition to ACI-35.030, AC Immune and Janssen Pharmaceuticals, Inc., are evaluating an exploratory alternative pTau vaccine candidate, JACI-35.054, in the current Phase 1b/2a trial. Based on encouraging interim safety, tolerability and immunogenicity results from the JACI-35.054 low-dose group, enrollment of a higher dose group has been initiated.

Prof. Philip Scheltens, Professor of Neurology at Amsterdam UMC Alzheimer Center and Principal Investigator of the Phase 1b/2a study, commented: “Pathological pTau can now be detected very early in the disease process, years before Tau deposits accumulate, enabling the identification of people at risk of developing AD. Therefore, a vaccine like ACI-35.030 might not only represent a breakthrough in AD therapy, but it could be part of a prevention strategy for AD.”

AC Immune is developing ACI-35.030 and JACI-35.054 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 the SupraAntigen™ platform

AC Immune’s clinically validated SupraAntigen™ platform uses proprietary liposomes to rapidly generate novel vaccines (SupraAntigen™-V) for active immunization as well as best-in-class monoclonal antibodies (SupraAntigen™-A) for passive immunization against key neurodegenerative disease targets. Antibodies generated by the platform are highly specific for the pathological conformations of misfolded proteins and have shown strong safety. The SupraAntigen™ platform has successfully generated two vaccines and two antibody candidates that have been validated in clinical studies and has led to multiple global partnerships with world-leading pharmaceutical companies. In addition to targeting Amyloid-beta and Tau, AC Immune has generated conformation-specific antibodies against emerging neurodegenerative disease targets including as alpha-synuclein, TDP-43 and the NLRP3 inflammasome pathway.

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

The Phase 1b/2a study 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 and JACI-35.054 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. This Phase 1b/2a study evaluating ACI-35.030 and JACI-35.054 was initiated in Q3 2019 and is currently ongoing.

About AC Immune SA

AC Immune SA is clinical-stage biopharmaceutical company that aims to become a global leader in precision medicine for neurodegenerative diseases, including Alzheimer’s disease, Parkinson’s disease, and NeuroOrphan indications driven by misfolded proteins. The Company’s two clinically validated technology platforms, SupraAntigen™ and Morphomer™, fuel its broad and diversified pipeline of first- and best-in-class assets, which currently features nine therapeutic and three diagnostic candidates, six of which are currently in clinical trials. AC Immune has a strong track record of securing strategic partnerships with leading global pharmaceutical companies including Genentech, a member of the Roche Group, Eli Lilly and Company, and Janssen Pharmaceuticals, Inc., resulting in substantial non-dilutive funding to advance its proprietary programs and >\$3 billion in potential milestone payments.

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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.