

## **AC Immune Announces Interim Phase 1b/2a Data Showing that its ACI-35.030 Anti-pTau Alzheimer's Vaccine Generates a Potent Immune Response**

*Observed strong induction of antibodies specific for pathological forms of Tau with ACI-35.030 treatment*

*New data presented at 14<sup>th</sup> CTAD conference support ACI-35.030's advancement into late-stage development*

**Lausanne, Switzerland, November 12, 2021** – AC Immune SA (NASDAQ: ACIU), a Swiss-based, clinical-stage biopharmaceutical company with a broad pipeline focused on neurodegenerative diseases, today presented new interim Phase 1b/2a data on ACI-35.030, a first-in-class anti-phosphorylated-Tau (pTau) vaccine candidate being developed in partnership with Janssen Pharmaceuticals, Inc., at the 14<sup>th</sup> Clinical Trials on Alzheimer's Disease (CTAD) conference, which is being held in Boston, Massachusetts from November 9-12, 2021.

ACI-35.030 is the first AD vaccine candidate designed to generate antibodies targeting pathological pTau in the brain. At CTAD, AC Immune's Chief Medical Officer Johannes Streffer gave an on-demand oral presentation featuring data from an ongoing, placebo-controlled Phase 1b/2a trial evaluating ACI-35.030 in participants with early Alzheimer's disease (AD). Results from the trial show that ACI-35.030 treatment led to the strong induction of antibodies specific for pathological forms of Tau such as pTau and its aggregated form, enriched paired helical filaments (ePHF).

### **Additional key findings from the CTAD presentation include:**

- Anti-pTau IgG titers increased by two orders of magnitude from baseline already two weeks after the first injection of the mid-dose of ACI-35.030
- Anti-ePHF IgG titers increased by one order of magnitude from baseline as early as two weeks after the second injection at week 8 of the mid-dose of ACI-35.030
- The anti-ePHF IgG response was boosted following additional doses at weeks 8 and 24
- The ACI-35.030-induced immune response was lasting over an initial period of 26-weeks and showed class-switching from IgM to IgG
- Interim safety data further support ACI-35.030's favorable safety and tolerability profile, with no clinically relevant safety concerns observed to date.

As previously announced, the ongoing Phase 1b/2a study has been expanded to include a total of 24 AD participants in the mid-dose sub-cohort. This expansion was designed to support the advancement of ACI-35.030 into late-stage development.

**Prof. Andrea Pfeifer, CEO of AC Immune SA, commented:** "To see such a strong and lasting immune response against a self-protein in an elderly population is both an exceptional finding and an important step towards shifting the AD treatment paradigm towards earlier treatment and

prevention. Pathological pTau is present in the CSF as a precursor many years before Tau accumulation is detectable via imaging techniques. By developing ACI-35.030 while leveraging cutting edge Tau diagnostics, we aim to deliver on the significant promise this anti-pTau vaccine has shown as a potential early intervention for AD. We look forward to continuing our collaboration with Janssen Pharmaceuticals, Inc. and to reporting additional immunogenicity data from the Phase 1b/2a trial's high-dose group."

**Prof. Philip Scheltens, Professor of Neurology at Amsterdam UMC Alzheimer Center and Principal Investigator of the Phase 1b/2a study, commented:** " These promising results provide important preliminary data, and these findings may aid in dose selection for later stage investigation. This information will be invaluable as we work to further ACI-35.030's clinical development and ultimately fulfill the hopes of clinicians and patients for a therapy that could delay, or even prevent, the onset of AD."

#### **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 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 dosages of ACI-35.030 and JACI-35.054 in participants 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 ten 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.

SupraAntigen<sup>®</sup> is a registered trademark of AC Immune SA in the following territories: AU, EU, CH, GB, JP and RU. Morphomer<sup>®</sup> is a registered trademark of AC Immune SA in CN, CH, GB, JP, and NO.

**For further information, please contact:**

**Media Relations**

Saoyuth Nidh  
AC Immune  
Phone: +41 21 345 91 34  
Email: [saoyuth.nidh@acimmune.com](mailto:saoyuth.nidh@acimmune.com)

**Investor Relations**

Yves Kremer, Ph.D.  
AC Immune  
Phone: +41 21 345 91 90  
Email: [yves.kremer@acimmune.com](mailto:yves.kremer@acimmune.com)

**U.S. Media**

Shani Lewis  
LaVoieHealthScience  
Phone: +1 609 516 5761  
Email: [slewis@lavoiehealthscience.com](mailto:slewis@lavoiehealthscience.com)

**U.S. Investors**

Corey Davis, Ph.D.  
LifeSci Advisors  
Phone: +1 212 915 2577  
Email: [cdavis@lifesciadvisors.com](mailto:cdavis@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. 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.