

## **AC Immune ACI-35.030 Phase 1b/2a Trial Interim Data Confirm Consistent Safety and Potent Immunogenicity of pTau Alzheimer's Vaccine in High-dose Cohort**

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

*ACI-35.030 continues to be well tolerated with no clinically relevant safety concerns observed in low-, mid- or high-dose cohorts to date*

*Interim data support plans for further late-stage development*

**Lausanne, Switzerland, February 15, 2022** – AC Immune SA (NASDAQ: ACIU), a Swiss-based, clinical-stage biopharmaceutical company with a broad pipeline focused on neurodegenerative diseases, today announced new interim 10-week data from the high-dose cohort of a placebo-controlled Phase 1b/2a trial evaluating ACI-35.030, a first-in-class phosphorylated-Tau (pTau) vaccine candidate in participants with early Alzheimer's disease (AD). The Company previously reported interim data from low-dose and mid-dose cohorts.

ACI-35.030, based on AC Immune's SupraAntigen® platform, is the first AD vaccine candidate designed to generate antibodies targeting pathological pTau in the brain. New interim data from the Phase 1b/2a trial show that the high-dose of ACI-35.030 led to the strong induction of antibodies selective for pTau and its aggregated form, enriched paired helical filaments (ePHF). These data are consistent with those [previously announced for the trial's mid-dose cohort](#) that showed median anti-pTau antibody titers increasing from baseline by two orders of magnitude at week 2 after a first injection.

### **Additional key findings from the high-dose interim analysis include:**

- Results indicate that the induced immune response selectively targets pTau, as shown by an increase in the anti-pTau/anti-Tau IgG ratio over time up to week 10.
- In this interim data set to week 10, median levels of antibodies reactive with pathological Tau (ePHF) were boosted with both the first and second vaccine injections.
- Safety data provide further support for ACI-35.030's favorable safety and tolerability profile, as no clinically relevant safety concerns have been 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 generate additional immunogenicity and safety data.

**Prof. Andrea Pfeifer, CEO of AC Immune SA, commented:** "These latest interim results add to the robust clinical dataset supporting plans for continued late-stage development. The observed antibody response also shows a preference for pathological pTau, which is present in AD years

before Tau accumulation can be detected via brain imaging. With these results we believe ACI-35.030 holds significant promise as a first-in-class therapeutic that could shift the AD treatment paradigm towards earlier treatment and prevention, especially when used alongside cutting-edge pTau diagnostics as part of a precision medicine approach. We look forward to the continued development of ACI-35.030.”

#### **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.

The pTau vaccine candidate is being developed in collaboration with Janssen Pharmaceuticals, Inc., part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

#### **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 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® is a registered trademark of AC Immune SA in the following territories: AU, EU, CH, GB, JP and RU. Morphomer® is a registered trademark of AC Immune SA in CN, CH, GB, JP, and NO.

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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.