

## AC Immune Announces First Positive Cognitive Results for a Tau-Targeting Monoclonal Antibody in Alzheimer's Disease

*Top-line data from Lauriet Phase 2 trial of semorinemab in mild-to-moderate AD shows a statistically significant reduction on one of two co-primary endpoints, ADAS-Cog11*

*First evidence of clinical activity in tau-targeting monoclonal antibody in MMSE 16-21 (mild-to-moderate) AD population*

*Partner Genentech to continue open label portion of the study and plans to submit top line results for presentation at November CTAD 2021 congress*

**Lausanne, Switzerland, August 31, 2021** – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today announced that Genentech, a member of the Roche Group, has informed the Company that Lauriet, a placebo-controlled Phase 2 study evaluating the safety and efficacy of the investigational anti-tau monoclonal antibody, semorinemab, in mild-to-moderate Alzheimer's disease (AD), met one of its co-primary endpoints, ADAS-Cog11. The second co-primary endpoint, ADCS-ADL, was not met. Safety data showed that semorinemab is well tolerated with an acceptable safety profile and no unanticipated safety signals.

Semorinemab demonstrated a statistically significant reduction in cognitive decline from baseline by 43.6% compared to placebo ( $p < 0.0025$ ) as measured by the Alzheimer's Disease Assessment Scale, Cognitive Subscale, 11-item Version (ADAS-Cog11) at week 49 in people with mild-to-moderate AD (i.e., Mini-Mental State Examination (MMSE) 16-21). There was no effect on the other co-primary endpoint of reducing the rate of functional decline from baseline as measured by the Alzheimer's Disease Cooperative Study-Activities of Daily Living (ADCS-ADL) or secondary efficacy endpoints for the Mini-Mental State Examination (MMSE) or the Clinical Dementia Rating-Sum of Boxes (CDR-SB). The safety was consistent with previous clinical data reported.

Genentech has reported that the open label portion of the study will continue as planned. Further analyses are ongoing, and top-line data will be submitted for presentation at the CTAD conference (Clinical Trials on Alzheimer's Disease conference) in November.

**Prof. Andrea Pfeifer, CEO of AC Immune SA, commented:** "The top line results of the Lauriet Phase 2 clinical trial of semorinemab are remarkable in that it is the first time we have seen a therapeutic effect by a monoclonal anti-Tau antibody therapy. We also are excited by the fact that this is the first time a monoclonal antibody has had a therapeutic impact on cognition in the mild-to-moderate AD patient population. Nevertheless, despite these interesting results, we are still cautious about what this may mean for patients as there was not an impact on the rate of functional decline or other efficacy endpoints. With that said, AD is a slow-moving chronic disease, and this small trial was relatively short, 49 weeks; so, the data from the open-label extension may be

important in elucidating the potential of semorinemab in this patient population. Scientifically, these data are encouraging for the therapeutic strategies targeting Tau. We look forward to additional data from our other clinical-stage Tau programs: Tau vaccine ACI-35, partnered with Janssen; and the small molecule Morphomer® Tau aggregation inhibitor, partnered with Eli Lilly.”

### **About the Lauriet study**

Lauriet is a double-blind, placebo-controlled, randomized Phase II trial assessing semorinemab, an investigational anti-tau monoclonal antibody, compared to placebo in 272 adult participants with mild-to-moderate AD across 43 study centers globally. The primary endpoints of the study evaluated the change from baseline at week 49 in cognition as measured by the Alzheimer’s Disease Assessment Scale, Cognitive Subscale, 11-Item Version (ADAS-Cog11) and the change from baseline in activities of daily living as measured by the Alzheimer’s Disease Cooperative Study-Activities of Daily Living (ADCS-ADL) scale. Secondary endpoints evaluated cognitive and functional measures including changes from baseline as measured by the Clinical Dementia Rating-Sum of Boxes (CDR-SB) and the Mini-Mental State Examination (MMSE). The Lauriet open label extension is ongoing. For more information, visit [ClinicalTrials.gov \(NCT03828747\)](https://clinicaltrials.gov/ct2/show/study/NCT03828747).

### **About semorinemab**

Semorinemab is an investigational monoclonal anti-tau antibody that targets the N-terminal portion of the tau protein, and is designed to bind to tau and slow its spread between neurons. In tauopathies such as AD, tau misfolds and forms tangles, which cause cell damage and ultimately neuronal death. It is hypothesized that abnormal tau protein then spreads between neurons, gradually involving more areas of the brain, and leading to clinical disease progression. Tau-targeting antibody therapies are designed to slow or stop this process of tau spread. Semorinemab is being developed by Genentech and was identified in collaboration with AC Immune (Nasdaq: ACIU, Lausanne, Switzerland). Semorinemab has been studied in two Phase 2 studies – Lauriet in mild-to-moderate AD and Tauriel in early (prodromal-to-mild) AD, where the primary efficacy endpoint was not met.

### **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 over \$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.

**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**

Katie Gallagher  
LaVoie Health Science  
Phone: +1 617 792 3937  
Email: [kgallagher@lavoiehealthscience.com](mailto:kgallagher@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.