

# AC Immune's ACI-24.060 Anti-Amyloid Beta Vaccine for Alzheimer's Shows Positive Initial Interim Safety and Immunogenicity in Phase 1b/2 ABATE Trial

- ACI-24.060 elicited an anti-Abeta antibody response in ABATE's first, low dose cohort
- ACI-24.060 was generally well tolerated with no safety concerns observed
- With these findings, dosing in the second, higher dose Alzheimer's cohort has begun
- Screening of cohort of study participants with Down syndrome also cleared to begin
- Further safety and immunogenicity findings from ABATE cohorts expected in H2 2023
- Initial data on amyloid plaque reduction measured via PET imaging anticipated in 2024

Lausanne, Switzerland, January 26, 2023 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today announced the first interim safety, tolerability and immunogenicity findings from the Phase 1b/2 ABATE trial of its anti-amyloid-beta (Abeta) vaccine ACI-24.060 in patients with prodromal Alzheimer's disease (AD). ABATE will now be expanded, as planned, to include individuals with Down syndrome (DS) and to evaluate higher doses in Alzheimer's patients.

Targeting Abeta using antibodies has recently been validated with FDA approvals of new monoclonal antibody treatments for patients with AD. By eliciting polyclonal anti-Abeta antibodies, the ACI-24.060 anti-Abeta vaccine development program aims to ultimately deliver significant benefits to patients, their caregivers, and healthcare systems in terms of potential safety and tolerability, low frequency dosing, low overall costs and durable responses.

Early results from the first cohort of AD patients in ABATE showed that low dose ACI-24.060 could elicit an anti-Abeta antibody response as soon as week 6 (2 weeks after the second injection). The data show that ACI-24.060 vaccination has been safe and well tolerated to date. As a result, dosing in ABATE's second, higher dose AD cohort has now begun and the trial is cleared to begin screening individuals with DS for part 2 of the study.

**Dr. Andrea Pfeifer, CEO of AC Immune SA, commented:** "We are delighted with the encouraging initial safety and immunogenicity findings for ACI-24.060 in ABATE reported today. We believe ACI-24.060's successful development could provide patients with a novel therapeutic option offering numerous potential advantages in treatment, maintenance, and prevention settings. These early findings from ABATE represent an important step towards this goal, and we look forward to reporting more detailed data at a future conference."

**Dr. Johannes Streffer, CMO of AC Immune SA, commented:** "ABATE's innovative design includes interim Abeta PET imaging analyses that can be benchmarked against the levels of plaque clearance achieved with clinically-validated monoclonal antibodies. This will provide an opportunity for early de-risking of ACI-24.060 and potentially a rapid transition to a pivotal program. Moreover, the inclusion of cohorts of participants with DS in the trial positions us to potentially address the needs of a vastly underserved vulnerable population, virtually all of whom will develop amyloid

plaques and AD. While looking forward to the trial's continued advancement and upcoming data readouts, I want to thank the participants and investigators for their participation and support."

### About the Phase 1b/2 ABATE Study (ClinicalTrials.gov Identifier: NCT05462106)

The ABATE study is a Phase 1b/2, multicenter, adaptive, double-blind, randomized, placebocontrolled study to assess the safety, tolerability, immunogenicity, and pharmacodynamic effects of ACI-24.060 in subjects with prodromal Alzheimer's disease and in adults with Down syndrome. All participants in the trial must have brain Abeta pathology confirmed by a positron emission tomography (PET) scan. The trial begins with a dose escalation phase in AD patients, during which various doses/dosing regimens may be evaluated, and also includes individuals with DS.

#### About ACI-24.060

ACI-24.060, derived from AC Immune's SupraAntigen® platform, has been shown in preclinical studies to induce a strong polyclonal antibody response that matures and is maintained against both oligomeric and pyroglutamate-Abeta species, key pathological forms of Abeta believed to drive Abeta plaque formation and disease progression. ACI-24.060 is designed to enhance the formation of broad-spectrum protective antibodies with the same safety and tolerability previously demonstrated in the ACI-24 program in Phase 1 and 2 trials. This investigational candidate has the potential to efficiently inhibit plaque formation and increase plaque clearance, and thereby may reduce or prevent disease progression.

## About AC Immune SA

AC Immune SA is a 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<sup>®</sup> and Morphomer<sup>®</sup>, fuel its broad and diversified pipeline of first- and best-in-class assets, which currently features ten therapeutic and three diagnostic candidates, five of which are currently in Phase 2 clinical trials and one of which is in Phase 3. 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 others, 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, RU, SG and USA. Morphomer® is a registered trademark of AC Immune SA in CN, CH, GB, JP, KR, NO and RU.

The information on our website and any other websites referenced herein is expressly not incorporated by reference into, and does not constitute a part of, this press release.

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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.