

## AC Immune Opens New Centers in Phase 1b/2 Trial Evaluating ACI-24 Targeting Abeta in Alzheimer's Disease and Down Syndrome

- Interim analysis expected around year-end 2022, informing Phase 2 start
- Trial progressing with regulatory clearances in the UK and also now in Spain
- Planned submission of U.S. Investigational New Drug application in Q1 2023
- Continues progress towards prevention of neurodegenerative diseases

**Lausanne, Switzerland, October 4, 2022** – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today provided an update on the Phase 1b/2 ABATE study of its anti-amyloid-beta (Abeta) vaccine candidate ACI-24.060 in patients with prodromal Alzheimer's disease (AD) and individuals with Down syndrome (DS). With regulatory clearances now in both the UK and Spain, clinical sites are open and recruiting.

**Dr. Andrea Pfeifer, CEO of AC Immune SA, commented:** “ACI-24.060 has been shown<sup>1,2</sup> to induce high levels of polyclonal antibodies against the two most toxic forms of Abeta, oligomeric Abeta and pyroGlu-Abeta, targeted by the clinically validated Abeta monoclonal antibodies, lecanemab and donanemab, respectively. It is thus a highly differentiated, strongly immunogenic, potentially best-in-class Abeta vaccine.”

ABATE is an ongoing two-part, multicenter, placebo-controlled phase 1b/2 trial evaluating the safety, tolerability, immunogenicity and pharmacodynamic effect of ACI-24.060. The biomarker-based design of the ABATE trial, with multiple interim analyses, will enable early and informed decision-making with rapid de-risking of the study and a safe transition into the more vulnerable DS population. Only patients with prodromal AD are enrolled in part 1, while part 2 focuses on individuals living with DS. AC Immune is preparing to submit a U.S. Investigational New Drug (IND) application in Q1 2023.

**Dr. Pfeifer, continued:** “AC Immune is committed to finding solutions for individuals with DS, virtually all of whom will develop Amyloid plaques leading to AD. ACI-24's strong immunogenicity against pathological Abeta targets positions this vaccine as a potentially best-in-class therapy with broad applicability across DS-related AD and other forms of AD. We are especially excited about this product given the recently reported positive Phase 3 data for an Abeta antibody, lecanemab, which provides unambiguous support for the amyloid hypothesis in AD. Our firm belief in amyloid has driven our investment in developing therapeutics that target Abeta – including ACI-24 and our monoclonal antibody crenezumab, in development with Genentech, a Roche company.”

**Prof. Johannes Streffer, CMO of AC Immune SA, commented:** “ABATE's innovative design allows us to gain crucial insights into the potential of active vaccination to halt neurodegeneration at its earliest stages. We expect these clinical insights will be pivotal for accelerating the

development of ACI-24.060 as well as our other clinical-stage vaccine candidates targeting phosphorylated-Tau and alpha-synuclein. All of these share the convenience of patient-friendly dosing with the promise of once or twice per year administration during maintenance.”

The first interim analysis of the Phase 1b part of the study is expected around the end of 2022, enabling progression into Phase 2 in individuals with DS. The combination of the two study populations, which display striking similarities in their biomarker patterns, provides important learnings between prodromal AD and individuals with DS, a population at extreme risk of developing AD. The trial design provides multiple opportunities to accelerate development, in terms of expansion of this study and the initiation of pivotal and prevention trials.

#### **References:**

1. Vukicevic et al, [An amyloid beta vaccine that safely drives immunity to a key pathological species in Alzheimer's disease: pyroglutamate amyloid beta](#), Brain Communications, Volume 4, Issue 1, 2022
2. Sol et al, [Biomarker-based development for optimized ACI-24, a novel candidate vaccine for the treatment and prevention of Alzheimer's disease](#), in-person-poster, AAIC congress, San Diego, CA, USA, July 31, 2022

#### **About the ABATE Phase 1b/2 Study**

The ABATE study is a phase 1b/2, multicenter, adaptive, double-blind, randomized, placebo-controlled 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 can be evaluated. Upon identification of an optimal dose and dosing regimen, the trial is planned to advance to an expansion phase in patients with AD and the initiation of the cohort in non-demented individuals living with DS.

#### **About ACI-24.060**

ACI-24.060, derived from AC Immune's SupraAntigen® platform, induces 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<sup>1,2</sup>. Importantly, antibodies against pyroglutamate Abeta have been shown to efficiently promote clearance of existing plaques in patients. 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® 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, RU and SG. Morphomer® is a registered trademark of AC Immune SA in CN, CH, GB, JP, NO and RU.

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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.