

## AC Immune Announces New Clinical Results in Down Syndrome and Plans for Future Development of Anti-Amyloid-Beta Vaccine

*Topline ACI-24 Phase 1b immunogenicity and safety results reported today at a global Down syndrome symposium*

*Reported new data in non-human primates for optimized vaccine formulation which shows strong response against key pathological Abeta species, including oligomeric and pyroglutamate Abeta*

**Lausanne, Switzerland, March 16, 2021** – AC Immune SA (NASDAQ: ACIU), a Swiss-based, clinical-stage biopharmaceutical company with a broad pipeline focused on neurodegenerative diseases, today announced plans to advance its novel anti-amyloid-beta (Abeta) vaccine into mid-stage clinical testing to treat and prevent the progression of Down syndrome (DS)-related Alzheimer’s disease (AD). Topline results reported today by AC Immune’s Chief Scientific Officer, Dr. Marie Kosco-Vilbois, at a [global DS symposium](#) co-sponsored by AC Immune, showed that ACI-24 demonstrated encouraging immunogenicity and safety in Phase 1b clinical testing in people with DS. The Company also disclosed new non-human primate data for an optimized formulation of the vaccine, which shows broad potential for the treatment and prevention of Abeta-driven diseases based on its superior efficacy in non-human primates.

**Dr. Kosco-Vilbois, commented:** “As World Down Syndrome Day approaches, which is held each year on March 21<sup>st</sup> to raise awareness for the DS community, we are proud to be leading the way towards addressing a key health challenge facing those living with DS, the early development of AD symptoms. Specifically, we are advancing our anti-Abeta vaccine, which demonstrated encouraging results in a first-of-its-kind Phase 1b study in people with DS. Importantly, the successful completion of this study demonstrates the feasibility of safely testing our Abeta vaccine in individuals with DS. The trial resulted in a very high retention rate with no early withdrawals, at any dose, during the treatment period. We look forward to continuing clinical development in order to potentially offer an effective vaccine strategy to treat, and perhaps ultimately prevent, the development of AD in individuals with DS.”

### Highlights from the Phase 1b study in DS-related AD

- Vaccination of adults with DS with ACI-24 resulted in encouraging immunogenicity (generation of anti-Abeta antibodies)
- A positive pharmacodynamic response was observed, as measured by an increase in plasma Abeta
- ACI-24 was safe and well tolerated with no serious adverse events (SAEs) reported
- There was no evidence of central nervous system (CNS) inflammation, meningoencephalitis, or ARIA (amyloid-related imaging abnormalities), including ARIA-E (-edema) and ARIA-H (-hemorrhage)
- AC Immune plans to present the full Phase 1b study results at the upcoming [Alzheimer’s Association International Conference \(AAIC\)](#)

Due to the high vulnerability of people with DS to severe Covid-19 sequelae, initiation of the next clinical trial will be delayed to ensure the safety of study participants. In the interim, AC Immune is taking advantage of this time to accelerate development of its optimized anti-Abeta vaccine formulation, which demonstrated encouraging safety and superior immunogenicity results in mouse and non-human primate (NHP) studies. Dr. Kosco-Vilbois presented some of these key findings during her presentation today:

**Key preclinical results for the optimized anti-Abeta vaccine formulation in NHPs**

- The optimized vaccine formulation primes, boosts, and maintains strong anti-Abeta antibody responses in two NHP species
- The optimized vaccine formulation generates conformation-specific antibodies targeting key pathological Abeta species, including oligomeric and pyroglutamate Abeta
- The antibodies elicited by the optimized vaccine formulation in NHPs showed clear target engagement by binding to human Abeta plaques on AD patient-derived brain tissue

ACI-24 is also currently being tested in a Phase 2 clinical trial in patients with mild AD. In this study, there have been no safety concerns nor evidence for CNS inflammation or ARIA related to ACI-24 in any subject. The Phase 2 study is progressing toward an 18-month interim analysis, which is planned for Q2 2021.

**Prof. Andrea Pfeifer, CEO of AC Immune SA, commented:** “There is broad potential for our optimized Abeta vaccine formulation across Abeta-driven diseases, including DS-related, genetic, and sporadic AD. We plan to complete the current Phase 2 study in mild AD and, in line with our proven business strategy, seek a strategic partner for further development for AD in the general population. This allows us to focus our in-house efforts on advancing our vaccine into later-stage clinical development to address genetically defined AD in people with DS. We look forward to initiating a follow-on clinical trial in DS as soon as the threat to this vulnerable patient population from Covid-19 subsides. In the interim, we are in discussions with the FDA on a potentially accelerated development pathway for the optimized vaccine formulation and expect to file an investigational new drug application for the new formulation in Q4 2021. In parallel, we are encouraged by the recent data from Abeta therapeutic antibodies in AD and expect our optimized vaccine formulation data showing strong responses against pathological oligomeric and pyroglutamate Abeta to further support ongoing clinical development in large and NeuroOrphan indications.”

**About AC Immune SA**

AC Immune SA is a Nasdaq-listed clinical-stage biopharmaceutical company, which aims to become a global leader in precision medicine for neurodegenerative diseases. The Company utilizes two proprietary platforms, SupraAntigen™ and Morphomer™, to design, discover and develop small molecule and biological therapeutics as well as diagnostic products intended to diagnose, prevent and modify neurodegenerative diseases caused by misfolding proteins. The Company's pipeline features nine therapeutic and three diagnostic product candidates, with six currently in clinical trials. It has collaborations with major pharmaceutical companies including Genentech, a member of the Roche Group, Eli Lilly and Company and Janssen Pharmaceuticals Inc.

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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.