AC Immune Reports Positive Interim Results from Phase 2 Trial of ACI-7104.056 Active Immunotherapy in Early Parkinson's Disease

- Active immunotherapy with ACI-7104.056 induces high anti-a-synuclein antibody levels on average 16-fold higher than placebo after 3 immunizations
- 100% of patients receiving ACI-7104.056 responded against the target antigen
- ACI-7104.056 is well tolerated with no clinically relevant safety issues reported to date

Lausanne, Switzerland, November 14, 2024 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision therapeutics for neurodegenerative diseases, today announced positive interim safety and immunogenicity data from the Phase 2 VacSYn clinical trial evaluating ACI-7104.056, its wholly owned anti-alpha-synuclein (a-syn) active immunotherapy candidate, for the treatment of patients with early Parkinson's disease (PD).

Dr. Andrea Pfeifer, CEO of AC Immune SA, commented: "We are encouraged by these initial Phase 2 safety and immunogenicity data on our ACI-7104.056 active immunotherapy being studied in early Parkinson's disease. The level of immunogenicity after only 3 months of treatment as well as the continued positive safety profile, reinforces the best-in-class characteristics of our clinically validated anti-a-syn active immunotherapy for the treatment of Parkinson's disease. We look forward to sharing further updates in H1 2025 including the decision to expand into Part 2 of the VacSYn study."

Dr. Pfeifer added, "As a leader in active immunotherapies for neurodegenerative diseases with two FDA Fast Track designated candidates, an important recognition of their promise, we are delighted with these initial VacSYn data. They further support the approach of using active immunotherapies to target the hallmark pathological proteins of neurodegenerative diseases, such as a-synuclein in Parkinson's disease, before irreversible damage occurs."

VacSYn is an adaptive, placebo-controlled, and biomarker-based Phase 2 study in patients with early PD, consisting of two parts with a seamless transition. Part 1 includes initial analyses from over 30 patients randomized to receive ACI-7104.56 or placebo at a ratio of 3:1. To date, no clinically relevant safety issues have been reported other than transient injection site reactions (49%) and headaches (18%).

Interim results show positive antibody responses were effectively induced against the target antigen at week 6 after 2 immunizations and were strongly boostable. Treatment with ACI-7104.056 induced an increase in anti-a-syn antibodies on average 16-fold higher than the placebo background level after three immunizations.

Based on further interim results to be reported in H1 2025 including pharmacodynamic data, AC Immune may decide to initiate Part 2 of VacSYn with up to 150 patients. Patients from Part 2 will also be evaluated for progression of motor and non-motor symptoms of the disease, as well as digital, imaging, and fluid biomarkers. The aim is to establish early proof-of-concept and identification of disease-specific biomarkers for rapid transition into a pivotal study.

About ACI-7104.056

ACI-7104.056 is an optimized formulation of its clinically validated anti-a-syn predecessor active immunotherapy which generated a target-specific antibody response against pathological oligomeric a-syn to inhibit spreading and downstream neurodegeneration in early Parkinson's disease. The accumulation of alpha-synuclein protein aggregates has been shown to cause inflammatory stress in cells and contribute to the degeneration of neurons in the brain. It has been known to play a key role in the development of neurodegenerative diseases such as Parkinson's Disease. Previous clinical studies showed the predecessor candidate produced a strong and boostable antibody response with evidence of target engagement and a signal of clinical efficacy.

About AC Immune SA

AC Immune SA is a clinical-stage biopharmaceutical company and a global leader in precision prevention 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 sixteen therapeutic and diagnostic programs, including five in Phase 2 development and one in Phase 3. AC Immune has a strong track record of securing strategic partnerships with leading global pharmaceutical companies, resulting in substantial non-dilutive funding to advance its proprietary programs and >$4.5 billion in potential milestone payments plus royalties.

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,"

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