AC Immune's ACI-35.030 (now "JNJ-2056") Granted FDA Fast Track Designation for Alzheimer's Disease

- Treatment of first randomized person with preclinical AD expected this quarter
- Phase 2b ReTain trial is fully funded and conducted by development partner

Lausanne, Switzerland, July 25, 2024 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today announced that its active-immunotherapy candidate, ACI-35.030 (now called JNJ-2056), targeting the pathologic form of the Tau protein, phosphorylated Tau (pTau), has received Fast Track designation from the U.S. Food and Drug Administration (FDA). The recently initiated Phase 2b clinical trial ReTain is currently recruiting participants with preclinical Alzheimer's disease, where individuals have yet to show clinical symptoms.

Dr. Andrea Pfeifer, CEO of AC Immune SA, commented: "Fast Track designation is an important recognition of the differentiation and potential value for patients of our anti-pTau active immunotherapy, ACI-35.030. The Phase 2b ReTain study is the first time any active immunotherapy is being tested in a preclinical AD population. We believe this modality has the potential to offer therapeutic advantages, as well as benefits in terms of convenience and access. Fast Track designation offers opportunities for more efficient development and regulatory review. More importantly, this underscores and validates the potential therapeutic impact of an active immunotherapy specifically targeting pTau, the key pathologic species of Tau protein. In Phase 1b/2a clinical testing, ACI-35.030 was shown to specifically target this toxic form of Tau and spare normal endogenous forms of the protein. We and our partners continue to drive innovation in the treatment and potential prevention of Alzheimer's disease, developing new mechanisms of action and first-in-class potential therapeutics that are safe and simple to use for the hundreds of millions of people living with or at risk of the disease."

JNJ-2056 is being developed pursuant to a global license, development and commercialization agreement with Janssen Pharmaceuticals, Inc. (Janssen), a Johnson & Johnson company. The ReTain trial is fully funded and conducted by Janssen.

About the ReTain Trial

The Phase 2b ReTain trial is a potentially registration-enabling randomized, multicenter, double-blind, placebo-controlled clinical study in participants with preclinical AD to assess the clinical effect of active immunization with JNJ-64042056. It is designed to test the hypothesis that JNJ-2056 has a disease-modifying effect that can delay or prevent the onset of cognitive impairment or other clinical symptoms in individuals with preclinical AD through inhibition of seeding and spreading of pathological Tau.

The study will include approximately 500 participants with preclinical AD (cognitively normal, Tau positive), who will be randomized in a 1:1 ratio to a single dose level of JNJ-2056 or placebo and administered as intramuscular injections for a maximum of 4 years. The primary endpoint will measure cognitive decline as assessed by the Preclinical AD Cognitive Composite 5 (PACC-5) score. The key secondary efficacy endpoint will assess the effect of JNJ-2056 on the propagation and/or accumulation of Tau pathology compared with placebo, as measured by Tau PET imaging.

About ACI-35.030 (JNJ-2056)

ACI-35.030, derived from AC Immune's SupraAntigen® platform, has been shown in clinical studies to induce a strong polyclonal antibody response that matures and is maintained against key pathological forms of Tau believed to drive Tau aggregation and disease progression. ACI-35.030 is designed to enhance the formation of broad-spectrum protective antibodies against pTau. This investigational candidate has the potential to reduce pathological Tau spreading in the early stages of AD, and thereby may reduce or prevent disease progression.

About AC Immune SA

AC Immune SA is a clinical-stage biopharmaceutical company and 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 sixteen therapeutic and diagnostic programs, 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, resulting in substantial non-dilutive funding in potential milestone payments plus royalties.

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.