

AC Immune Receives Second Milestone Payment Following Progress in Phase 2b ReTain Trial of ACI-35.030 in Preclinical Alzheimer's Disease

- Prescreening rate of Phase 2b ReTain trial triggers clinical development milestone payment in September
- Potentially registrational trial is targeting enrollment of approximately 500 participants with pre-symptomatic AD
- FDA Fast Track designation granted in July for ACI-35.030 (now "JNJ-2056") for AD

Lausanne, Switzerland, September 17, 2024 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision therapeutics for neurodegenerative diseases, today announced that it will receive the second ReTain-related milestone payment (CHF 24.6 million) under its agreement with Janssen Pharmaceuticals, Inc. (Janssen), a Johnson & Johnson company.

The milestone payment has been triggered by the rapid rate of prescreening in the potentially registrational Phase 2b ReTain trial investigating active-immunotherapy candidate ACI-35.030 (now called "JNJ-2056") to treat preclinical (pre-symptomatic) Alzheimer's disease (AD). With last December's milestone payment, this brings the total milestone payments received for ACI-35.030 related to this trial to CHF 40 million.

Dr. Andrea Pfeifer, CEO of AC Immune SA, commented: "This early milestone demonstrates that the medical community and members of the public believe, as we do, that second generation therapeutics for Alzheimer's disease, like our active immunotherapy targeting pathological phosphorylated-Tau protein (pTau), may provide an important benefit to those diagnosed early, prior to the development of disease symptoms. Early diagnosis and treatment are needed to combat neurodegeneration.

"This payment also re-affirms the quality and productivity of AC Immune's technology platforms and drug development capabilities. We have now received a total of approximately CHF 425 million in milestone and upfront payments from all of our collaboration deals to date, and there are outstanding potential milestone payments exceeding CHF 4.3 billion, plus royalties on potential sales. Importantly, in these challenging financial markets, this milestone payment adds to our already solid financial position, providing us with three years of cash for operations, in which time we expect to achieve several potentially transformational milestones."

JNJ-2056 received Fast Track designation from the U.S. Food and Drug Administration (FDA) in July, an important recognition of its differentiation and its potential value for patients. It is the second active immunotherapy from AC Immune to achieve this regulatory milestone, after ACI-24.060,

which targets Abeta. AC Immune's PI-2620 Tau-PET diagnostic, which is in Phase 3 development, also received Fast Track designation this August.

ACI-35.030 has been shown in Phase 1b/2a clinical testing to induce an antibody response targeting pTau while sparing normal endogenous forms of Tau. ReTain has attracted a high level of interest among potential participants with the rate of prescreening outperforming expectations.

"The Phase 2b ReTain trial is a potentially important step in the fight against neurodegeneration, as it is the first time any active immunotherapy is being tested in the preclinical AD population. Active immunotherapies like ACI-35.030 could offer therapeutic advantages, together with improved convenience and access, and the recent Fast Track designation is an important recognition of its potential value for patients," **Dr. Pfeifer said.**

About the Phase 2b ReTain Study (ClinicalTrials.gov Identifier: [NCT06544616](https://clinicaltrials.gov/ct2/show/study/NCT06544616))

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 (JNJ-2056). 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. It is currently being conducted at more than 40 clinical trial sites in the U.S., Japan, UK and Australia, and more are expected to open shortly.

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.

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

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 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.

For further information, please contact:

SVP, Investor Relations & Corporate Communications

Gary Waanders, Ph.D., MBA
AC Immune
Phone: +41 21 345 91 91
Email: gary.waanders@acimmune.com

U.S. Investors

Corey Davis, Ph.D.
LifeSci Advisors
Phone: +1 212 915 2577
Email: cdavis@lifesciadvisors.com

International Media

Chris Maggos
Cohesion Bureau
Phone: +41 79 367 6254
Email: chris.maggos@cohesionbureau.com

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. 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.