UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

# FORM 6-K

## REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of December, 2023

**Commission file number: 001-37891**

# AC IMMUNE SA

(Exact Name of Registrant as Specified in Its Charter)

**EPFL Innovation Park**
**Building B**
**1015 Lausanne, Switzerland**
(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

On December 15, 2023, AC Immune SA (the "Company") issued a press release announcing that its development partner has programmed the launch of a Phase 2b clinical study to evaluate ACI-35.030 (JNJ-64042056) in patients with preclinical AD, those individuals not yet showing symptoms. Under the terms of the licensing agreement with Janssen Pharmaceuticals, Inc. (Janssen), a Johnson & Johnson company, the Company will now receive a milestone payment of CHF 15 million and is eligible to receive another milestone payment of CHF 25 million related to achieving a non-disclosed enrollment target. A copy of the press release is attached as Exhibit 99.1 to this Report on Form 6-K.

This Report on Form 6-K (other than Exhibit 99.1 hereto) shall be deemed to be incorporated by reference into the registration statements on Form F-3 (File No. 333- 255576, File No. 333-227016 and File No. 333-249655) and Form S-8 (File No. 333-233019) of AC Immune SA and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

**EXHIBIT INDEX**

| Exhibit Number | Description |
| --- | --- |
| 99.1 | Press Release, dated December 15, 2023 |

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**AC IMMUNE SA**

By: /s/ Andrea Pfeifer
Name: Andrea Pfeifer
Title: Chief Executive Officer

By: /s/ Christopher Roberts
Name: Christopher Roberts
Title: Vice President, Finance and Interim Chief Financial Officer

Date: December 15, 2023

**PRESS RELEASE**

# AC Immune's Targeted Anti-pTau Active Immunotherapy for Alzheimer's Disease Advances into Phase 2b Trial

- Potentially registration-enabling Phase 2b study (ReTain) will evaluate the effect of ACI-35.030 on cognition and Tau pathology in approximately 500 participants with preclinical Alzheimer's disease (AD)
- Anti-pTau active immunotherapy being designed to potentially prevent or reduce cognitive decline could address need of over 315 million people globally[1] with preclinical AD
- AC Immune to receive approximately CHF 40 million in total milestone payments under terms of the licensing agreement, following trial initiation and enrollment milestone

**Lausanne, Switzerland, December 15, 2023** – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today announced that its development partner has programmed the launch of a Phase 2b clinical study to evaluate ACI-35.030 (JNJ-64042056) in patients with preclinical Alzheimer's disease (AD), those individuals not yet showing symptoms. ACI-35.030 is an investigational targeted active immunotherapy, selective for pathological phosphorylated Tau (pTau). Studies have shown that pTau correlates with AD progression and the trial aims to show that ACI-35.030 can prevent or slow down the progression of tau pathology and onset of clinical symptoms.

Under the terms of the licensing agreement with Janssen Pharmaceuticals, Inc. (Janssen), a Johnson & Johnson company, AC Immune will now receive a milestone payment of CHF 15 million and will receive another milestone payment of CHF 25 million related to achieving a non-disclosed enrollment target. The partnership with Janssen aims to develop and commercialize therapeutic anti-Tau active immunotherapies for the treatment of AD and potentially other Tauopathies.

**Dr. Andrea Pfeifer, CEO of AC Immune SA, commented:** "In the recently completed Phase 1b/2a trial, data showed that ACI-35.030 was able to activate patients' immune systems with a robust polyclonal antibody response against phosphorylated Tau and its neurotoxic aggregated form, which is believed to contribute to the pathology and progression of Alzheimer's disease. Our partner's decision to move forward with this robust clinical trial shows that treatment with this active immunotherapy so early in the disease process that individuals are not yet showing symptoms, holds tremendous promise to slow or possibly even prevent progression to symptomatic AD."

The Phase 2b ReTain trial is a potentially registration-enabling trial and is a randomized, multicenter, double-blind, placebo-controlled clinical study in participants with preclinical AD to assess the clinical effect of active immunization with ACI-35.030. It is designed to test the hypothesis that ACI-35.030 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.

- Approximately 500 participants with preclinical AD (cognitively normal, amyloid positive, Tau positive) will be randomized in a 1:1 ratio to a single dose level of ACI-35.030 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, which combines tests that evaluate episodic memory, timed executive function, and global cognition. It is sensitive enough to detect early changes in cognitive function, even before the first clinical signs of mild cognitive impairment (MCI) are apparent[2].
- The key secondary efficacy endpoint will assess the effect of ACI-35.030 on the propagation and/or accumulation of Tau pathology compared with placebo, as measured by Tau PET imaging in the Tau Naïve Composite region of interest. PET imaging for pathological Tau will be performed at baseline and annually for 4 years. This endpoint may be sufficient for a Biologics License Application (BLA) filing seeking accelerated approval from the U.S. Food & Drug Administration (FDA), with the primary endpoint serving as the basis for a traditional approval.


1. *Gustavsson et al. Alzheimer's and Dement. 2023 19:658-670. https://doi.org/10.1002/alz.12694*
2. *Donohue MC, Sperling RA, Salmon DP, Rentz DM, Raman R, Thomas RG, Weiner M, Aisen PS, Australian Imaging, Biomarkers, and Lifestyle Flagship Study of Ageing, Alzheimer's Disease Neuroimaging Initiative, and Alzheimer's Disease Cooperative Study (2014) The preclinical Alzheimer cognitive composite: measuring amyloid-related decline. JAMA Neurol 71(8):961–970. https://doi.org/10.1001/jamaneurol.2014.803*


**About ACI-35.030 (JNJ-64042056)**

ACI-35.030 (JNJ-64042056) is an investigational active immunotherapy designed using AC Immune's SupraAntigen® platform. Its liposomal formulation incorporates a conformationally-constrained, membrane bound target peptide antigen, phosphorylated Tau (pTau), in addition to adjuvants and non-Tau T-helper peptides. Immunization with ACI-35.030 has been shown in a recent Phase 1b/2a clinical trial to rapidly elicit antibodies after the first injection against extracellular pathological pTau in 100% of elderly patients with Alzheimer's disease. Importantly, the antibody response was sustained, boostable, and focused on pathological pTau, including enriched paired helical filaments (ePHF). Aggregation of pTau leads to the formation of neurotoxic ePHF and Tau tangles. Antibodies against non-phosphorylated Tau diminished over time. To date, no safety or tolerability issues have been observed following ACI-35.030 immunization.

**About the SupraAntigen® platform**

AC Immune's clinically validated SupraAntigen® platform uses proprietary liposomes to rapidly generate novel product candidates for active immunotherapy as well as best-in-class monoclonal antibodies for passive immunization against key neurodegenerative disease targets. Antibodies generated by the platform are highly specific for the pathological conformations of misfolded proteins and have shown strong safety. The SupraAntigen® platform has successfully generated two active immunotherapies and two antibody candidates that have been validated in clinical studies and has led to multiple global partnerships with world-leading pharmaceutical companies. In addition to targeting Amyloid-beta and Tau, AC Immune has generated conformation-specific antibodies against emerging neurodegenerative disease targets including alpha-synuclein, TDP-43, and the NLRP3 inflammasome pathway.

**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, 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 including Genentech, a member of the Roche Group, Eli Lilly and Company, and others, 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, 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:**

**Head of 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. 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.