

## **AC Immune Receives FDA Fast Track Designation for Anti-Alpha-synuclein Active Immunotherapy, ACI-7104, to Treat Early Parkinson's Disease (PD)**

- Ongoing Phase 2 VacSYn study to expand to sites in USA with Investigational New Drug (IND) clearance
- Recent positive interim results showed safety and immunogenicity with early signals of activity
- Full week-100 results from Part 1 of VacSYn trial expected in H2 2026

**Lausanne, Switzerland, August 11, 2026** – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company developing targeted therapeutics for neurodegenerative diseases, today announced that it has received Fast Track designation and clearance of its Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) for its wholly owned anti-alpha-synuclein (a-syn) active immunotherapy candidate, ACI-7104, for the treatment of early-stage Parkinson's disease (PD).

ACI-7104 is designed to induce a-syn-specific antibodies, preferentially recognizing aggregated a-syn species that are toxic to neurons. The candidate is currently being investigated in the VacSYn Phase 2 trial, an adaptive, biomarker-based study in patients with early-stage Parkinson's disease, with final Part 1 week-100 results on track to be announced in H2.

**Martin Zügel, interim CEO of AC Immune SA, commented:** *"Fast Track designation and IND clearance from the FDA are important achievements for ACI-7104, one of our wholly-owned programs, given its potential to address the significant unmet need in Parkinson's. We look forward to working closely with the FDA as we advance ACI-7104 through its ongoing clinical development towards potentially delivering a much-needed treatment option for patients."*

FDA Fast Track designation reflects the early interim Phase 2 data demonstrating safety, tolerability and immunogenicity, and providing first signals that targeting underlying a-syn pathology with an active immunotherapy could potentially impact PD. The interim results, reported for Part 1 of the study at 76 weeks, successfully demonstrated ACI-7104 was safe and well tolerated, with no clinically relevant safety issues being reported. Targets were also met for immunogenicity with a 100% responder rate. AC Immune recently announced a \$4 million research grant from the Vijay and Marie Goradia Charitable Foundation to support the extension of Part 1 of the VacSYn trial, enabling the assessment of long-term safety and efficacy of ACI-7104 for an additional two years.

**Günther Staffler, Executive Vice President, Development at AC Immune SA, commented:** *"ACI-7104 represents a promising active immunotherapy designed to target pathological a-syn for the treatment of prodromal and early PD. The FDA's decision signifies the growing importance of the program including the positive interim Phase 2 findings. This is a key regulatory milestone for the program, and we look forward to delivering the full results from Part 1 of the VacSYn trial in the coming months."*

**About ACI-7104**

ACI-7104 is an optimized formulation of AC Immune's anti-a-syn predecessor active immunotherapy which generated an 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 contributes to the degeneration of neurons in the brain, linking it to the development of neurodegenerative diseases such as Parkinson's Disease.

**About AC Immune SA**

AC Immune (NASDAQ: ACIU) is a clinical stage biopharmaceutical company developing a pipeline of products, including both active immunotherapies and small molecules, targeting key misfolded proteins and pathways for the treatment of multiple neurodegenerative diseases. The company has a growing focus on its wholly owned proprietary clinical-stage programs, including: ACI-7104, an active immunotherapy targeting  $\alpha$ -synuclein ( $\alpha$ -syn) in Parkinson's disease; and ACI-19764, a small molecule inhibitor of the NLRP3 inflammasome. In addition, an early-stage small molecule development program targeting intracellular a-syn is advancing towards the clinic.

ACIU has a strong track record of securing strategic partnerships with leading global pharmaceutical companies, resulting in substantial non-dilutive funding and >\$4.5 billion in potential milestone payments. ACIU's pharma-partnered programs, all in Alzheimer's disease, include: a collaboration on ACI-24, an active immunotherapy targeting Abeta; a collaboration on ACI-35 targeting phospho-Tau; and a collaboration developing brain-penetrant small molecule drugs targeting intracellular pathologic Tau.

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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.*