AC Immune Receives FDA Fast Track Designation for Anti-Amyloid-beta Active Immunotherapy, ACI-24.060, to Treat Alzheimer's Disease

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- Ongoing Phase 1b/2 ABATE study enrolling well and expanding to sites in USA with Investigational New Drug (IND) clearance for ACI-24.060
- Dosed first individual with Down syndrome (DS) in the DS cohort of ABATE
- Interim safety and immunogenicity data in Alzheimer's disease (AD) and DS cohorts expected in H2 2023
- Initial PET data on amyloid plaque reduction in AD expected H1 2024

Lausanne, Switzerland, June 27, 2023 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today announced that it has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for its wholly-owned anti-amyloid beta (Abeta) active immunotherapy (vaccine)-candidate, ACI-24.060, for treatment of Alzheimer's disease. This follows FDA clearance of the Investigational New Drug (IND) application enabling expansion to the USA of the ongoing Phase 1b/2 ABATE study of ACI-24.060 in patients with AD and individuals with DS. Furthermore, the first individual with DS has been dosed in ABATE.

Dr. Andrea Pfeifer, CEO of AC Immune SA, commented: "We are delighted to see the quality and importance of our ACI-24.060 program reflected in the granting of Fast Track designation, which offers opportunities for expedited development and regulatory review. This regulatory progress underscores the attraction of an active immunotherapy targeting toxic species of Abeta. By inducing a polyclonal response including antibodies against both oligomeric Abeta and pyroglutamate-Abeta, ACI-24.060 targets the same toxic species as disease modifying anti-Abeta monoclonal antibodies that slowed AD progression in Phase 3 clinical trials. As ACI-24.060, created using our SupraAntigen® platform, specifically targets the most toxic forms of Abeta, we believe it may offer best-in-class efficacy with all the potential advantages in safety, administration and distribution that can be expected from a vaccine. We look forward to showing in H1 2024 the effect of ACI-24.060 on amyloid plaque reduction, a surrogate marker for disease modification."

ACI-24.060's Fast Track designation and IND clearance, as well as the expansion of ABATE to include individuals with DS were supported by positive initial interim safety and immunogenicity data from ABATE's first, low dose AD cohort. Dosing in a second, higher dose AD cohort began earlier this year.

Dr. Johannes Streffer, CMO of AC Immune SA, commented: "ABATE's expansion into the USA will allow us to accelerate the trial's advancement and build upon the strong momentum we've generated in Europe. With today's announcement, we remain firmly on track to report additional interim safety and immunogenicity data later this year, and for the crucial interim readout of Abeta-PET imaging data in AD in the first half of next year. By benchmarking the amount of Abeta plaque reduction achieved with ACI-24.060 against those achieved with FDA-approved monoclonal antibodies, we believe we can generate early evidence of our vaccine's therapeutic potential to support its expeditious advancement towards pivotal programs in AD and DS-related AD."

Dr. Michael Rafii, Medical Director of the Alzheimer's Therapeutic Research Institute, Professor of Neurology at the Keck School of Medicine, and the Principal Investigator of the trial commented: "Despite representing the world's largest population that is genetically at high risk for AD, individuals with DS are vastly underserved and underrepresented in clinical trials. I applaud AC Immune for seeking to address the urgent needs of this population and believe ACI-24.060 holds great promise as a novel therapy that can lower Abeta plaques to delay, or perhaps even prevent, the onset of clinical dementia symptoms in AD and DS-related AD. Moreover, I believe the potential safety, efficacy, and logistical advantages of a vaccine over monoclonal antibodies strongly support the development of therapeutics such as ACI-24.060 as the next generation of anti-Abeta therapies."

About the Phase 1b/2 ABATE Study (ClinicalTrials.gov Identifier: NCT05462106)
The ABATE study is a Phase 1b/2, multicenter, adaptive, double-blind, randomized, placebo-controlled study to assess the safety, tolerability, immunogenicity, and pharmacodynamic effects of ACI-24.060 in subjects with prodromal Alzheimer's disease and in adults with Down syndrome. All participants in the trial must have brain Abeta pathology confirmed by a positron emission tomography (PET) scan. Recent clinical studies and FDA approvals have validated Abeta as a disease modifying therapeutic target in AD and are supportive of Abeta PET imaging as a surrogate marker of efficacy. The trial begins with a dose escalation phase in AD patients, during which various doses/dosing regimens may be evaluated, and also includes individuals with DS.

About AD in Down syndrome
Individuals with Down syndrome (DS) have a third copy of all or part of chromosome 21, which contains the gene that codes for amyloid-precursor protein (APP). Overproduction of APP is believed to cause the accumulation of Abeta plaques. Virtually all individuals with DS will develop Abeta plaques and AD[1], with DS-related AD sharing a similar pathophysiology and biomarkers with other forms of genetic AD. Given the more predictable onset and progression of symptoms in DS-related AD, AC Immune believes ABATE's results will offer crucial insights into the ability of ACI-24.060 active immunotherapy to modulate neurodegeneration at its earliest stages and offer this population a much needed therapeutic option.

About ACI-24.060
ACI-24.060, derived from AC Immune's SupraAntigen® platform, has been shown in preclinical studies to induce a strong polyclonal antibody response that matures and is maintained against both oligomeric and pyroglutamate-Abeta species, key pathological forms of Abeta believed to drive Abeta plaque formation and disease progression. ACI-24.060 is designed to enhance the formation of broad-spectrum protective antibodies with the

same safety and tolerability previously demonstrated in the ACI-24 program in Phase 1 and 2 trials. This investigational candidate has the potential to efficiently inhibit plaque formation and increase plaque clearance, and thereby may reduce or prevent disease progression.

Reference

1. Lott, Ira T., and Elizabeth Head. "Dementia in Down syndrome: unique insights for Alzheimer disease research." *Nature Reviews Neurology* 15.3 (2019): 135-147.

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.

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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.

Attachment

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