

# AC Immune Presents Full Phase 1b Results on Anti-Abeta Vaccine and Discusses its First-in-Class Diagnostic for Parkinson's Disease at AAIC 2021

ACI-24 generated an encouraging immune response that correlated with a signal of target engagement in patients with Down syndrome (DS)

Full Phase 1b results support the continued clinical development of anti-Abeta vaccine approaches in DS-related Alzheimer's disease (AD)

**Lausanne, Switzerland, July 29, 2021** – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today outlined two presentations being delivered at the <u>Alzheimer's Association International Conference</u> (AAIC) 2021, taking place both in Denver, USA and virtually from July 26-30, 2021.

The presentations highlight precision medicine approaches to enable the early detection and prevention of neurodegenerative diseases by targeting amyloid beta (Abeta) and alpha-synuclein (a-syn). The first virtual oral presentation includes the full results from a first-of-its-kind Phase 1b clinical trial evaluating the anti-Abeta vaccine ACI-24 in adults with DS. Previously announced topline data from the trial showed that ACI-24 generated evidence of immunogenicity along with a positive pharmacodynamic response and a favorable safety and tolerability profile.

The Phase 1b study results showed that ACI-24 was safe and well tolerated in adults with DS. No serious adverse events or evidence of central nervous system (CNS) inflammation, meningoencephalitis, or ARIA (amyloid-related imaging abnormalities), including ARIA-E (edema) and ARIA-H (hemorrhage), were reported. Data also showed that administration of ACI-24 resulted in encouraging immune responses that correlated with increases in plasma Abeta, which are indicative of target engagement.

**Dr. Michael Rafii, Medical Director of the Alzheimer's Therapeutic Research Institute and Associate Professor of Neurology at the Keck School of Medicine, Lead Investigator of the study, commented:** "Individuals with DS represent a homogenous genetic population that are predisposed to AD, which highlights the value of this landmark Phase 1b study and the innovation in AC Immune's approach. Importantly, the results of this study show a signal of target engagement that correlates with immune response against Abeta and support the continued evaluation of anti-Abeta vaccine approaches in these patients. This may enable a shift towards earlier treatment and ultimately prevention of AD, and would be a critical advance as the damage neurons undergo in neurodegenerative diseases cannot be reversed by currently available therapies."

**Prof. Andrea Pfeifer, CEO of AC Immune SA, commented:** "The full data set from our Phase 1b DS study are promising and highlight AC Immune's expertise in active vaccination approaches for neurodegenerative disease. Based on these results, we plan to advance an optimized formulation of ACI-24 into late-stage clinical testing to treat and prevent the progression of DS-related AD. This

formulation has demonstrated enhanced immunogenicity against the two most toxic Abeta species in non-human primates, positioning it to be a potential breakthrough in Abeta vaccination. We look forward to the program's continued advancement, which we believe will be accelerated by the recent validation of Abeta as a surrogate trial endpoint in AD."

**Prof. Johannes Streffer, CMO of AC Immune SA, commented:** "Through an active vaccination approach, we aim to prevent neurodegeneration rather than simply slow its progression. As almost all subjects with DS go on to develop AD-like symptoms, this is an ideal patient population in which to gain critical insights and expertise into the development of vaccines for a variety of neurodegenerative diseases. We thus expect the promising results and learnings from this trial to accelerate the advancement of not only our ACI-24 program, but our entire world-leading pipeline of active vaccines for neurodegeneration."

In addition, AC Immune is also presenting a poster on ACI-12589, a first-in-class positron emission tomography (PET) imaging tracer targeting a-syn that is being developed as a first-in-class diagnostic for Parkinson's disease (PD). Previously reported preclinical data confirm that the Morphomer®-derived candidate has a desirable brain-PET ligand pharmacokinetic profile in non-human primates. These and other prior data demonstrating ACI-12589's signal specificity on tissue samples from patients with alpha-synucleinopathies, including PD, multiple system atrophy (MSA) and dementia with Lewy bodies (DLB) are being discussed in this poster presentation.

**Prof. Pfeifer continued,** "Through the development of companion diagnostics such as ACI-12589 in PD, we are working to better enable the advancement of the neurodegenerative disease treatment paradigm towards earlier treatment and prevention. We expect the continued development of this program, alongside the advancement of our recently acquired industry-leading anti-a-syn vaccine, to solidify our position at the forefront of PD drug development. We are pleased to have the opportunity to discuss ACI-12589 with the scientific community at AAIC ahead of the anticipated readout from its first-in-human study later this quarter."

# Scientific updates at AAIC, July 26–30, 2021

Title:	ACI-24 in adults with Down syndrome: Results of a Phase 1b, randomized placebo-controlled study (3 Star Trial)
Date:	Thursday, July 29, 2021   10:00 am - 11:15 pm MT
Presenter:	Oral presentation by Dr. Michael S. Rafii, Alzheimer's Therapeutic
	Research Institute, Keck School of Medicine of University of Southern
	California
Title:	[18F]ACI-12589, a novel alpha-synuclein radiotracer as a biomarker
	in patients with Parkinson's disease and other synucleinopathies
Date:	July 26–30, 2021
Presenter:	Poster presentation by Dr. Francesca Capotosti, AC Immune SA

### About AC Immune SA

AC Immune SA is 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, six of which are currently in clinical trials. 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 Janssen Pharmaceuticals, Inc., 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

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