AC Immune Reports Second Quarter 2023 Financial Results and Provides a Corporate Update

- Received FDA Fast Track Designation for ACI-24.060 anti-amyloid-beta (Abeta) active immunotherapy to treat Alzheimer's disease (AD)
- Enrollment in ongoing Phase 1b/2 ABATE study of ACI-24.060 in AD and Down syndrome (DS) is on track and expanding to sites in USA following IND clearance, dosed first individual with DS
- Next interim safety and immunogenicity data from AD and DS cohorts in ABATE expected in H2 2023
- Results of amyloid plaque reduction analysis (Abeta-PET) after treatment with ACI-24.060 in ABATE study expected in H1 2024; these results could potentially provide an opportunity to accelerate into a registrational program
- Cash position of CHF 93.0 million finances the Company into Q3 2024, excluding the benefit of anticipated milestone payments

Lausanne, Switzerland, August 4, 2023 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today reported results for the second quarter ended June 30, 2023, and provided a corporate update.

Dr. Andrea Pfeifer, CEO of AC Immune SA, commented: "We entered the second half of 2023 with strong momentum. ACI-24.060's Fast Track designation acknowledges its potential as a next-generation anti-Abeta active immunotherapy positioned to offer best-in-class efficacy, an improved safety profile, and fewer administration and distribution constraints compared to monoclonal antibodies. With our ABATE trial enrolling AD patients in Europe and expanding the DS cohort via US sites, ACI-24.060 is moving expeditiously towards additional interim safety and immunogenicity data, and Abeta-PET imaging analyses on amyloid plaque reduction in AD in the first half of 2024. Demonstration of Abeta plaque clearance, a validated surrogate marker for clinical efficacy, would provide a major opportunity to rapidly transition to a registrational program."

"We also look forward to the initiation of the next AD trial of ACI-35.030, the anti-pTau (phosphorylated Tau) active immunotherapy later this year, to be followed by a milestone payment. The progress of our programs affirms our commitment to developing precision medicine approaches to improve outcomes for patients, and ultimately, to prevent progression of neurodegenerative diseases through earlier diagnosis and early intervention."

Q2 2023 and Subsequent Highlights

- [Received Fast Track designation](#) from the U.S. Food and Drug Administration (FDA) for ACI-24.060, AC Immune's wholly-owned SupraAntigen®-based anti-Abeta active immunotherapy candidate, for the treatment of AD.

- Ongoing Phase 1b/2 ABATE study of ACI-24.060 in patients with AD and individuals with DS is on track and expanding to sites in the USA following FDA Investigational New Drug (IND) clearance.
- The first participant with DS was dosed in the Phase 1b/2 ABATE trial.
- The first patient with Parkinson's disease was dosed in the Phase 2 VacSYn clinical trial evaluating ACI-7104.056, AC Immune's wholly-owned anti-alpha-synuclein (a-syn) active immunotherapy.
- Several programs were showcased at the annual Alzheimer's Association International Conference (AAIC 2023), which included a poster detailing ABATE's trial design, a "Perspectives Session" focused on TDP-43 proteinopathy in neurodegenerative diseases organized by AC Immune scientists, and an oral presentation showing detailed data on ACI-12589, a novel positron emission tomography (PET) tracer targeting a-syn.
- The TDP-43-PET tracer program has progressed as planned and a clinical candidate has been selected. Over the coming months further preclinical work will be completed to permit the initiation of a first in human study in 2024.
- A peer-reviewed paper describing our therapeutic antibody candidate targeting TDP-43 was published in the journal 'mAbs'.
- Initiated a research collaboration with Prof. Michael Heneka, director of the Luxembourg Centre for Systems Biomedicine, University of Luxembourg, to further evaluate the therapeutic potential of AC Immune's SupraAntigen®- and Morphomer®-derived inhibitors of the NLRP3-ASC inflammasome pathway in preclinical disease models.
- Hosted a webinar on early diagnosis and prevention of AD featuring presentations by key opinion leaders Kaj Blennow, MD, PhD, of University of Gothenburg and Sahlgrenska University Hospital, and Giovanni Frisoni, MD, of University of Geneva and the Memory Clinic at Geneva University Hospital. To view a replay of the webinar, click here.
- Announced the appointment of new Chief Medical Officer, Nuno Mendonça, MD.

Anticipated Milestones

ACI-24.060 anti-Abeta active immunotherapy	• Additional interim safety and immunogenicity data from AD cohorts of ABATE study expected in H2 2023 • Interim safety and immunogenicity data from DS cohort of ABATE study expected in H2 2023 • Initial Abeta-PET data on amyloid plaque reduction in AD expected in H1 2024
ACI-7104.056 anti-a-syn active immunotherapy	• Completion of recruitment of first cohort in the Phase 2 VacSYn study in Parkinson's disease expected in H2 2023
ACI-35.030 anti-pTau active immunotherapy	• Initiation of next trial in AD expected in H2 2023 (to be followed by a milestone payment)
Semorinemab anti-Tau antibody	• Results from the open-label extension of the Phase 2 Lauriet trial in mild-to-moderate AD expected in H2 2023

Anti-TDP-43 antibody	• Advancement of candidate into preclinical development (tox) expected in H2 2023
a-syn-PET tracer	• Declaration of next clinical candidate for development in Parkinson's disease expected in H2 2023

Analysis of Financial Statements for the Quarter Ended June 30, 2023

- **Cash Position:** The Company ended Q2 with a total cash balance of CHF 93.0 million (CHF 122.6 million as of December 31, 2022), composed of CHF 40.0 million in cash and cash equivalents and CHF 53.0 million in short-term financial assets. The Company's cash balance provides sufficient capital resources to progress into at least Q3 2024 without considering receipt of potential future milestone payments.

- **R&D Expenditures:** R&D expenses for the three months ended June 30, 2023, were CHF 13.7 million compared to CHF 15.7 million in the comparable period in 2022. The decrease was due mainly to lower discovery and preclinical expenses.

- **G&A Expenditures:** G&A decreased by CHF 0.7 million to CHF 3.7 million, mostly due to a decrease in personnel expenses.

- **Other Operating Income:** The Company recognized CHF 0.3 million in grant income from Michael J. Fox Foundation and Target ALS grants.

- **IFRS Loss for the Period:** The Company reported a net loss after taxes of CHF 16.8 million for the three months ended June 30, 2023, compared with a net loss of CHF 19.6 million for the comparable period in 2022.

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 sixteen therapeutic and diagnostic programs, 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.

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Forward looking statements

Condensed Consolidated Balance Sheets (Unaudited)
(In CHF thousands)

	As of	
	June 30, 2023	**December 31, 2022**
Assets		
Non-current assets		
Property, plant and equipment	3,760	4,259
Right-of-use assets	2,539	2,808
Intangible asset	50,416	50,416
Long-term financial assets	361	361
Total non-current assets	57,076	57,844
Current assets		
Prepaid expenses	5,167	4,708
Accrued income	675	408
Other current receivables	303	392
Short-term financial assets	53,000	91,000
Cash and cash equivalents	40,007	31,586
Total current assets	99,152	128,094
Total assets	156,228	185,938
Shareholders' equity and liabilities		
Shareholders' equity		
Share capital	1,800	1,797
Share premium	433,699	431,323
Treasury shares	(110)	(124)
Currency translation differences	(6)	10
Accumulated losses	(296,055)	(264,015)
Total shareholders' equity	139,328	168,991
Non-current liabilities		
Long-term lease liabilities	1,976	2,253
Net employee defined-benefit liabilities	3,771	3,213
Total non-current liabilities	5,747	5,466
Current liabilities		
Trade and other payables	1,352	929
Accrued expenses	8,818	9,417
Deferred income	430	587
Short-term lease liabilities	553	548
Total current liabilities	11,153	11,481
Total liabilities	16,900	16,947
Total shareholders' equity and liabilities	156,228	185,938

Condensed Consolidated Statements of Income/(Loss) (Unaudited)
(In CHF thousands, except for per-share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenue				
Contract revenue	—	—	—	—
Total revenue	—	—	—	—
Operating expenses				
Research & development expenses	(13,682)	(15,692)	(27,555)	(30,815)
General & administrative expenses	(3,681)	(4,374)	(7,787)	(8,550)
Other operating income/(expense), net	317	207	725	677
Total operating expenses	(17,046)	(19,859)	(34,617)	(38,688)
Operating loss	(17,046)	(19,859)	(34,617)	(38,688)
Financial income	259	—	468	—
Financial expense	(27)	(126)	(124)	(279)
Exchange differences	(16)	345	(67)	485
Finance result, net	216	219	277	206
Loss before tax	(16,830)	(19,640)	(34,340)	(38,482)
Income tax expense	(3)	(3)	(6)	(7)
Loss for the period	(16,833)	(19,643)	(34,346)	(38,489)
Loss per share:	(0.20)	(0.23)	(0.41)	(0.46)

Condensed Consolidated Statements of Comprehensive Income/(Loss) (Unaudited)
(In CHF thousands)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Loss for the period	(16,833)	(19,643)	(34,346)	(38,489)
Items that will be reclassified to income or loss in subsequent periods (net of tax):				
Currency translation differences	(8)	39	(16)	49
Items that will not to be reclassified to income or loss in subsequent periods (net of tax):				
Remeasurement gains on defined-benefit plans	—	7,381	—	7,381
Total comprehensive loss (net of tax)	(16,841)	(12,223)	(34,362)	(31,059)