

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

 <u>Received Fast Track designation</u> 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 <u>expanding to sites in the USA</u> 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 <u>showcased</u> 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 <u>here</u>.
- <u>Announced</u> the appointment of new Chief Medical Officer, Nuno Mendonça, MD.

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

Anticipated Milestones

Anti-TDP-43	•	Advancement of candidate into preclinical development (tox)
antibody		expected in H2 2023
a-syn-PET tracer	٠	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

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. Forwardlooking 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.

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

December 31 2022
4,259
2,808
50,416
361
57,844
4,708
408
392
91,000
31,586
128,094
185,938
1,797
431,323
(124
10
(264,015
168,991
2,253
3,213
5,466
929
9,417
587
548
11,481
16,947
185,938
100,900

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)
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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)