AC Immune Reports Full-Year 2020 Financial Results and Provides 2021 R&D Outlook

March 23, 2021

- Anti-pTau Alzheimer's vaccine delivers potent immunogenicity in ongoing Phase 1b/2a study, supporting further development into Phase 2/3
- Anti-Abeta Alzheimer's vaccine advancing based on Phase 1b safety and immunogenicity results in Down syndrome; further interim results expected in Q2 for Phase 2 in Alzheimer's disease
- Morphomer™ Tau aggregation inhibitor achieves target brain exposure in Phase 1; program advancing in NeuroOrphan indications and Alzheimer's disease
- First-in-class alpha-synuclein PET diagnostic to report clinical results in Q3 2021
- Advancing multiple candidates targeting the NLRP3 inflammasome pathway for CNS and non-CNS indications
- Ongoing strong financial position of CHF 225.9 million in cash ensures the Company is fully financed through Q1 2024, excluding potential incoming milestones

LAUSANNE, Switzerland, March 23, 2021 (GLOBE NEWSWIRE) -- AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today reported its financial results for the year ended December 31, 2020. The Company also provided an overview of its execution strategy and anticipated clinical and preclinical milestones for 2021, as well as the strong progress being made across its broad portfolio of therapeutic and diagnostic product candidates.

Prof. Andrea Pfeifer, CEO of AC Immune SA, commented: "We began 2021 with strong momentum based on the effective execution of our multi-pronged clinical development growth strategy. This is exemplified by our anti-pTau vaccine, which recently demonstrated highly potent immune responses against pathological Tau and remarkable safety in patients with early Alzheimer's disease (AD). We are also creating future value by accelerating development of our proprietary, first-in-class candidates addressing novel targets in neurodegeneration, such as our promising alpha-synuclein PET tracer, which will generate initial clinical results this year, and our highly valued programs targeting the NLRP3 inflammasome. Our strong track record shows that expanding our efforts to advance these key early-stage programs may lead to multiple future opportunities for strategic partnership as well as in-house clinical development for select indications. In parallel, we continue to collaborate with our global partners to advance our later-stage clinical programs toward key inflection points. Looking forward in 2021, we expect to build upon our successes and continue innovating as a leader in precision medicine for neurodegenerative disease."

2020 and Q1 2021 Research & Development Highlights

Clinical Pipeline advancement

- Reported promising interim Phase 1b/2a results for ACI-35.030, a novel anti-phospho-Tau (pTau) vaccine candidate showing strong safety and high titers of antigen-specific antibodies in 100% of older patients with early AD. The study is currently enrolling patients into the highest dose group, with further clinical readouts expected this year.
- Advanced next-generation alpha-synuclein positron emission tomography (PET) tracer candidate, ACI-12589, into a first-in-human clinical study, with an expected data readout in Q3 2021
- Reported topline Phase 2 results for semorinemab, the Company's investigational monoclonal anti-Tau antibody candidate for the treatment of prodromal to mild AD, partnered with Genentech, a member of the Roche Group. These represent the first-ever Phase 2 results for an anti-Tau antibody therapeutic in AD. Primary completion of the second Phase 2 study in moderate AD patients is expected in Q2 2021.
- Completed a Phase 1 clinical study in healthy volunteers for ACI-3024, an oral small molecule Morphomer™ Tau aggregation inhibitor, which achieved target brain exposure. The Companies have decided to pursue other promising Tau Morphomer candidates from AC Immune's research platform for potential clinical development in AD. ACI-3024 will be further evaluated for efficacy in models of rare Tauopathies.

Partnership milestone payments and grants

- Received a CHF 10 million milestone payment from Eli Lilly and Company related to ACI-3024
- Amended the collaboration agreement with Lilly for Tau Morphomers to include a new CHF 60 million Phase 2 milestone payment, which increased the total potential deal value by CHF 40 million to CHF 1.86 billion
- Received multiple prestigious and highly competitive grants in 2020 focused on acceleration of the Company's proprietary and potentially game-changing diagnostic programs

- Won Ken Griffin Alpha-synuclein Imaging Competition from The Michael J. Fox Foundation for Parkinson's Research (MJFF) and is able to receive together with its clinical partner USD 3.2 million (CHF 3.1 million) to support AC Immune's alpha-synuclein-PET tracers
- Awarded a EUR 1.45 million grant to support the partnership between AC Immune and the EU Joint Programme – Neurodegenerative Disease Research (JPND) ImageTDP-43 Consortium to advance its first-in-class TAR DNA-binding protein 43 (TDP-43) PET tracers
- Awarded a USD 600,000 grant from Target ALS to develop novel immuno-assays to detect pathological TDP-43 in cerebrospinal fluid (CSF) and blood based on AC Immune's SupraAntigen™-derived anti-TDP-43 antibodies

Strengthening of Management and Board

- Appointed Prof. Johannes R. Streffer, former UCB Biopharma Head of Translational Neuroscience, to the new role of Chief Medical Officer
- Welcomed Prof. Carl H. June, world authority on immune tolerance and adoptive immunotherapy, to the Company's Board of Directors
- Appointed renowned Neurologist with a specific focus in the emerging field of Down syndrome (DS)-related Alzheimer's disease, Dr. Juan Fortea to AC Immune's Clinical Advisory Board

Future Value Creation

- Reported key advancements for several therapeutic programs targeting the NLRP3 inflammasome, including small molecule inhibitors, which showed the first evidence of *in vivo* activity in a model of peripheral inflammation, as well as high-affinity monoclonal antibodies that bind extracellular components of the (NOD)-like receptor protein 3 (NLRP3) pathway and inhibit inflammasome-mediated immune response *in vitro*
- Identified and characterized the first biologically active small molecule Morphomer alpha-synuclein aggregation inhibitors, which significantly decreased alpha-synuclein aggregate formation in cellular assays by interfering with the fibrillation process
- Strengthened strategic partnership with WuXi Biologics to accelerate advancement of TDP-43 antibody into clinical development for NeuroOrphan indications

2021 execution strategy to maximize value creation

AC Immune's execution strategy is focused on three key initiatives, which support the Company's overarching goal of enabling precision medicine for neurodegenerative diseases:

- The Company plans to accelerate the development of its late-stage therapies in AD in collaboration with its strategic partners, including its novel pTau vaccine with Janssen Pharmaceuticals Inc., which continues to show great promise.
- AC Immune is sharpening its strategic focus on non-AD indications with high unmet need. Currently this includes its anti-Abeta vaccine in people with DS, as well as its therapeutic and diagnostic candidates targeting TDP-43 and alpha-synuclein, where the Company may focus in-house efforts on select NeuroOrphan indications while seeking potential partnerships for larger indications like LATE (limbic-predominant age-related TDP-43 encephalopathy) and Parkinson's disease (PD). Furthermore, AC Immune's NLRP3 inflammasome-targeted programs have broad applicability both within central nervous system (CNS) and non-CNS indications.
- The Company plans to accelerate advancement of its diagnostic candidates to late-stage development, as continued leadership in precision medicine is a key differentiator for AC Immune. These candidates include its Tau, alpha-synuclein, and TDP-43 PET tracers, which potentially enable earlier disease diagnosis, improved clinical trial outcomes and additional revenue generation for the Company.

Anticipated 2021 milestones
Clinical Milestones

- ACI-35.030 anti-pTau vaccine: reported Phase 1b/2a in AD interim results in Q1 (second highest dose); further Phase 1b/2a interim analysis in Q4 (highest dose)
- JACI-35.054 alternative anti-pTau vaccine: Phase 1b/2a in AD interim analysis in Q2 (low dose)
- Alpha-synuclein imaging agent: advanced third-generation candidate to first-in-human clinical study in Q1; readout expected in Q3
- ACI-24 anti-Abeta vaccine in DS: reported Phase 1b top line results in Q1; to present further study results at the Alzheimer's Association International Conference® 2021 in Q2
- ACI-24 in AD: reported Phase 2, 12-month interim analysis in Q1; 18-month interim analysis in Q2
- Semorinemab anti-Tau antibody: Phase 2 trial primary completion (estimated last patient, last visit) in moderate AD in Q2
- ACI-3024 small molecule Morphomer Tau aggregation inhibitor: select NeuroOrphan indication for further development in Q2
- ACI-24 in DS: submit investigational new drug (IND) application for optimized vaccine formulation in Q4

Preclinical Milestones

- Alpha-synuclein small molecule inhibitor: identified first biologically active small molecule in Q1; start *in vivo* proof-of-concept studies in Q3
- TDP-43 imaging agent: initiate investigational new drug (IND)-enabling studies in Q3
- Morphomer NLRP3-ASC: report *in vivo* proof-of-concept results in a non-CNS disease model and begin *in vivo* proof-of-concept studies with validated candidate in CNS in Q4
- Anti NLRP3-ASC antibody: begin *in vivo* proof-of-concept studies in Q4
- Anti-TDP-43 antibody: initiate IND-enabling toxicology studies in Q4
- TDP-43 biofluid diagnostic: establish validation-ready assay in Q4

Therapeutic and Diagnostic Pipeline Overview

AC Immune also provided a comprehensive overview highlighting strong progress across its clinical and preclinical development pipeline. This supplemental material can be viewed and downloaded in the investor section of the Company's website.

Analysis of Financial Statements for the year ended December 31, 2020

- **Cash Position:** The Company had a total cash balance of CHF 225.9 million, comprised of CHF 160.9 million in cash and cash equivalents and CHF 65 million in short-term financial assets. This compares to a total cash balance of CHF 288.6 million as of December 31, 2019. The decrease of CHF 62.7 million is principally due to continued investments in our R&D pipeline. The total shareholders' equity position decreased to CHF 215.5 million from CHF 272.4 million as of the prior year. The Company's cash balance provides enough capital resources to progress through at least Q1 2024 without potential incoming milestone payments.
- **Contract Revenues:** Contract revenues for the year ended December 31, 2020 totaled CHF 15.4 million compared to CHF 110.5 million in 2019, representing a CHF 95 million decrease. The Company recognized a CHF 10 million milestone and CHF 4.3 million for research and development activities in 2020 from its Lilly agreement compared to CHF 103.1 million for an upfront payment and milestone and CHF 2.6 million for research and development activities in 2019.
- **R&D Expenditures:** R&D expenses increased by CHF 9.1 million for the year ended December 31, 2020.
  - **Discovery and preclinical expenses:** The Company increased expenditures across a variety of its discovery and preclinical programs. These include investments to advance the second generation of our ACI-24 for Down Syndrome project, the initiation of IND-enabling studies of our anti-TDP-43 antibody project and various other investments across our alpha-synuclein and neuroinflammation programs.
  - **Clinical expenses:** The Company also increased expenditures across multiple Clinical programs. These include investments to prepare a follow-on trial for our Abeta vaccine for Down Syndrome project, additional enrollment costs for the Phase 1b/2a study for ACI-35.030 and a full year of clinical activities to complete the Phase 1 of our Morphomer Tau asset in partnership with Lilly.
  - **Salary- and benefit-related costs:** The Company's salary- and benefit-related costs increased by CHF 2.7 million, primarily due to the addition of 13 FTEs, annualization of 2019 hires and increases in share-based compensation.
- **G&A Expenditures:** For the year ended December 31, 2020, G&A increased by CHF 2.5 million to 18.6 million. Of this increase, CHF 1.7 million is due to salary- and benefit-related costs, primarily due to the addition of 3 FTEs, annualization of 2019 hires and increases in share-based compensation. Additionally, the Company incurred a CHF 0.8 million increase in other G&A expenses, predominantly associated with depreciation expense, insurance and professional fees
- **IFRS Income/(Loss) for the Period:** The Company reported a net loss after taxes of CHF 61.9 million for the year ended December 31, 2020, compared with net income of CHF 45.4 million for 2019

2021 Financial Guidance

For the full year 2021, the Company expects its total cash burn to range between CHF 65 million –75 million.

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 nine 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
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.

Balance Sheets
(In CHF thousands)

	As of December 31,	
	2020	**2019**
ASSETS		
Non-current assets		
Property, plant and equipment	4,416	3,917
Right-of-use assets	2,223	2,255
Long-term financial assets	334	304
Total non-current assets	6,973	6,476
Current assets		
Prepaid expenses	3,954	2,788
Accrued income	1,591	1,095
Other current receivables	329	304
Short-term financial assets	65,000	95,000
Cash and cash equivalents	160,893	193,587
Total current assets	231,767	292,774
Total assets	238,740	299,250
SHAREHOLDERS’ EQUITY AND LIABILITIES		
Shareholders’ equity		
Share capital	1,538	1,437
Share premium	346,890	346,526
Treasury shares	(100)	—
Accumulated losses	(132,850)	(75,521)
Total shareholders’ equity	215,478	272,442
Non-current liabilities		
Long-term lease liabilities	1,780	1,813
Net employee defined benefit liabilities	7,464	7,485
Total non-current liabilities	9,244	9,298
Current liabilities		
Trade and other payables	2,184	142
Accrued expenses	11,085	11,797
Deferred income	306	4,477
Short-term financing obligation	—	652
Short-term lease liabilities	443	442
Total current liabilities	14,018	17,510
Total liabilities	23,262	26,808
Total shareholders’ equity and liabilities	238,740	299,250

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

	For the Years Ended December 31,		
	2020	**2019**	**2018**
Revenues			
Contract revenue	15,431	110,456	6,912
Total revenue	15,431	110,456	6,912
Operating expenses			
Research & development expenses	(59,487)	(50,432)	(44,277)
General & administrative expenses	(18,557)	(16,058)	(12,467)
Other operating income/(expense)	1,353	570	282
Total operating expenses	(76,691)	(65,920)	(56,462)
Operating income/(loss)	(61,260)	44,536	(49,550)
Financial income	78	303	127
Financial expense	(184)	(1,926)	(334)
Change in fair value of conversion feature	—	4,542	—
Exchange differences	(555)	(2,013)	(1,194)
Finance result, net	(661)	906	(1,401)
Income/(loss) before tax	(61,921)	45,442	(50,951)
Income tax expense	—	—	—
Income/(loss) for the period	(61,921)	45,442	(50,951)
Earnings/(loss) per share:			
Basic income/(loss) for the period attributable to equity holders	(0.86)	0.64	(0.82)
Diluted income/(loss) for the period attributable to equity holders	(0.86)	0.64	(0.82)

Statements of Comprehensive Income/(Loss)
(In CHF thousands)

	For the Years Ended December 31,		
	2020	**2019**	**2018**
Income/(loss) for the period	(61,921)	45,442	(50,951)
Other comprehensive income/(loss) not to be reclassified to income or loss in subsequent periods (net of tax)			
Remeasurement income/(losses) on defined benefit plans (net of tax)	726	(1,304)	(302)
Total comprehensive income/(loss), net of tax	(61,195)	44,138	(51,253)

Reconciliation of income/(loss) to adjusted income/(loss) and earnings/(loss) per share to adjusted earnings/(loss) per share

	For the Years Ended December 31,		
In CHF thousands, except for share and per share data	**2020**	**2019**	**2018**
Income/(loss)	**(61,921)**	**45,442**	**(50,951)**
Adjustments:			
Non-cash share-based payments[1]	4,088	2,834	2,518
Foreign currency (gains)/losses[2]	703	826	1,179
Effective interest expenses[3]	—	1,355	—
Change in fair value of conversion feature[4]	—	(4,542)	—
Adjusted income/(loss)	**(57,130)**	**45,915**	**(47,254)**
Earnings/(loss) per share – basic	(0.86)	0.64	(0.82)
Earnings/(loss) per share – diluted	(0.86)	0.64	(0.82)
Adjustment to earnings/(loss) per share – basic	0.07	0.01	0.06
Adjustment to earnings/(loss) per share – diluted	0.07	0.00	0.06

Adjusted earnings/(loss) per share – basic	**(0.79)**	**0.65**	**(0.76)**
Adjusted earnings/(loss) per share – diluted	**(0.79)**	**0.64**	**(0.76)**
Weighted-average number of shares used to compute adjusted loss per share – basic	71,900,212	70,603,611	61,838,228
Weighted-average number of shares used to compute adjusted loss per share – diluted	71,900,212	71,103,341	61,838,228

[1]Reflects non-cash expenses associated with share-based compensation for equity awards issued to directors, management and employees of the Company. This expense reflects the awards' fair value recognized for the portion of the equity award which is vesting over the period.

[2]Reflects foreign currency re-measurement gains and losses for the period, predominantly impacted by the change in the exchange rate between the US Dollar and the Swiss Franc.

[3]Effective interest expense for the period relates to the accretion of the Company's convertible loan in accordance with the effective interest method.

[4]Change in fair value of conversion feature that is bifurcated from the convertible loan host debt with Lilly.

Adjustments for the years ended December 31, 2020, 2019 and 2018 decreased net loss by CHF 4.8 million, increased net income by CHF 0.5 million and decreased net loss by CHF 3.7 million, respectively. The Company recorded share-based compensation expenses of CHF 4.1 million, CHF 2.8 million and CHF 2.5 million for the years ended December 31, 2020, 2019 and 2018, respectively. There were foreign currency re-measurement losses of CHF 0.7 million, CHF 0.8 million and CHF 1.2 million for the years ended December 31, 2020, 2019 and 2018, respectively, predominantly related to the cash balance of the Company as a result of fluctuations of the US Dollar against the Swiss Franc. Related to the Company's convertible note settled with Lilly in 2019, we recorded CHF 1.4 million for amortization of effective interest for the year ended December 31, 2019 and recognized a CHF 4.5 million gain for the change in fair value of the liability related to the conversion feature in 2019. There were no comparable expenses or gains in 2020 nor 2018.



Source: AC Immune SA