AC Immune Reports Full-Year 2019 Financial Results and Provides 2020 R&D Outlook

March 30, 2020

- Ongoing strong financial position with CHF 288.6 million in cash, ensuring the Company is fully financed through Q1 2024, excluding potential incoming milestones
- Received CHF 110 million in upfront and development milestone payments and a USD 50 million equity note in 2019 as a result of the Morphomer™Tau Lilly partnership
- Added new potential CHF 60 million Phase 2 initiation milestone and achieved CHF 10 million milestone in Q1 2020 in Lilly partnership
- Five clinical milestones expected in 2020 including the first Phase 2 readout of an anti-Tau antibody in Alzheimer's disease (AD)
- Initiated three clinical trials targeting Tau and a substudy within the ongoing Phase 2 Alzheimer's Prevention Initiative trial

LAUSANNE, Switzerland, March 30, 2020 (GLOBE NEWSWIRE) -- AC Immune SA (NASDAQ: ACIU), a Swiss-based, clinical-stage biopharmaceutical company with a broad pipeline focused on neurodegenerative diseases, today announced financial results for the year ended December 31, 2019, and provided a business and 2020 research and development outlook.

Prof. Andrea Pfeifer, CEO of AC Immune SA, commented: "AC Immune is building on clinical and business accomplishments in 2019, and anticipates multiple clinical, value-creating milestones in 2020. We anticipate reporting data from two studies of our proprietary anti-Abeta vaccine program, ACI-24 as well as Phase 1 results for the small molecule Morphomer™ Tau aggregation inhibitor, ACI-3024, in partnership with Eli Lilly and Company.

Prof. Pfeifer continued: "In parallel, our heritage as a leader in delivering cutting-edge science enables our Company to advance novel preclinical therapeutic and diagnostic candidates focused on emerging targets and neuroinflammation towards the clinic, setting the stage for additional value creation and partnership opportunities. AC Immune's leading position in the field is built upon our proprietary discovery technology platforms, SupraAntigen™ and Morphomer™, as well as our personalized medicine approach and exceptional development execution."

2019 and Q1 2020 Research & Development Highlights
Successful execution in preclinical and clinical development during 2019 resulted in a stronger pipeline.

- A Phase 1 study is ongoing for ACI-3024, a first-in-class investigational oral small molecule Morphomer™ Tau specific aggregation inhibitor that will be studied in neurodegenerative diseases characterized by the presence of pathological Tau aggregates. The initial CHF 60 million milestone payment has been modified such that Lilly has paid AC Immune CHF 30 million during Q3 2019 and CHF 10 million in Q1 2020; and, AC Immune now is eligible for a new additional milestone payment of CHF 60 million within 60 days after dosing of the first patient in the first Phase 2 clinical trial of a Morphomer™ Tau in the United States or European Union. The amendment to the financial terms increases the total deal value by CHF 40 million to CHF 1.86 billion, up from CHF 1.82 billion.
- Initiation of a second Phase 2 trial of semorinemab in patients with moderate AD, by our collaboration partner Genentech, a member of the Roche Group. This antibody is also being studied in a separate Phase 2 trial in prodromal to mild AD
- Received a milestone payment from our collaboration partner, Life Molecular Imaging, in connection with the initiation of a Phase 2 study in AD of the Tau positron emission tomography (PET) tracer PI-2620
- Initiation of a Phase 1b/2a clinical trial in early AD to evaluate the anti-phospho-Tau vaccine, ACI-35.030, which targets pathological Tau and is intended as a disease-modifying treatment for AD and other Tauopathies in collaboration with Janssen Pharmaceuticals, Inc
- Initiation of a substudy by our partner Genentech, a member of the Roche Group, within the ongoing Phase 2 Alzheimer's Prevention Initiative (API) trial of AC Immune's investigational candidate, crenezumab. This substudy aims to measure Tau burden using PET in order to increase the understanding of disease progression in the preclinical stage of autosomal dominantly inherited AD
- Presented initial interim data from an on-going Phase 1b trial of the ACI-24 anti-Abeta vaccine to treat Down syndrome (DS)-related AD
- Discontinuation by our collaboration partner Roche of the CREAD and CREAD 2 Phase 3 studies of the anti-beta-amyloid antibody, crenezumab, in people with prodromal to mild sporadic AD
- Established a research collaboration with leading scientists at the Perelman School of Medicine, University of Pennsylvania focused on studying the pathological mechanisms of TDP-43 misfolding and aggregation

- Awarded a new grant from The Michael J. Fox Foundation (MJFF) for development of AC Immune's pioneering alpha-synuclein PET tracers
- Hosted two Key Opinion Leader (KOL) events focused on "untangling" Tau pathology as an important therapeutic and diagnostic target for AD and other neurodegenerative diseases, and on treating DS-related AD

2020 Research & Development Outlook
The coming years will be transformational for the field of neuroscience and AC Immune is poised to make significant clinical contributions, capturing substantial interest and value in 2020 and beyond. The Company will deliver multiple near-term catalysts, including results from five clinical trials. The Company's sustained growth is driven by its industry-leading *Roadmap to Successful Therapies for Neurodegenerative Diseases*, and is fueled by its proprietary technology platforms, SupraAntigen™ and Morphomer™, which continue to generate therapeutic antibody, small molecule and vaccine candidates.

2020 Clinical Readouts

- Semorinemab, anti-Tau antibody: Phase 2 trial primary completion (estimated last patient, last visit) in prodromal/mild in Q2
- ACI-24 anti-Abeta vaccine in DS: Phase 1b full study reporting in H2
- ACI-35.030 anti-pTau vaccine: Phase 1b/2a in AD interim analysis in Q2
- ACI-3024 small molecule Morphomer™ Tau aggregation inhibitor: Phase 1 results in healthy volunteers in Q2; data disclosed by partner in H2 (expected)
- ACI-24 in AD: Phase 2, 12-month interim analysis in H2

2020 Preclinical Milestones

- Alpha-synuclein antibody: started investigational new drug (IND)-enabling studies for lead candidate in Q1
- Anti-TDP-43 antibody: declare clinical lead and start IND-enabling studies in Q2
- Alpha-synuclein small molecule: identify first biologically active small molecule in Q2
- Alpha-synuclein imaging agent: advance third generation candidate to clinical stage in Q4
- Neuroinflammation: declare lead candidates for small molecule and antibody programs in Q4

Prof. Pfeifer concluded: "In summary, 2020 begins a decade with the potential for major neuroscience advances. With AC Immune's remarkably broad development pipeline focused on neurodegenerative diseases we have multiple opportunities to contribute to the advancement of this field from a business, clinical and human perspective."

Analysis of Financial Statements for the year ended December 31, 2019

- **Cash Position:** The Company had a total cash balance of CHF 288.6 million, comprised of CHF 193.6 million in cash and cash equivalents and CHF 95 million in short-term financial assets. This compares to a total cash balance of CHF 186.5 million as of December 31, 2018. The increase of CHF 102.1 million is principally due to the CHF 80 million upfront payment, USD 50 million convertible equity note and CHF 30 million milestone payment related to the agreement with Lilly. The total shareholders' equity position increased to CHF 272.4 million from CHF 177.6 million as of the prior year. The Company's cash balance provides enough capital resources to progress through at least Q1 2024
- **Revenues:** Revenues for the year ended December 31, 2019 totaled CHF 111.0 million. This represents an increase of CHF 103.8 million compared to 2018. The increase for the year end relates to the recognition of CHF 75.7 million from the right-of-use license and research and development activities linked to the 2018 Lilly agreement and a CHF 30 million payment for the first milestone achieved with Lilly. Additionally, the Company recorded a EUR 2 million (CHF 2.2 million) in connection with the initiation of a Phase 2 trial in AD of Tau PET Tracer with Life Molecular Imaging
- **R&D Expenditures:** R&D expenses increased by CHF 6.2 million to CHF 50.4 million for the year ended December 31, 2019. Of this increase, CHF 1.7 million relates to increases in R&D expenses directly allocated to R&D programs such as a CHF 0.9 million increase related to higher research, preclinical and manufacturing costs for the lead alpha-synuclein antibody and a CHF 0.7 million increase for manufacturing and preparation of the Phase 2 study for ACI-24 for DS. Additionally, the personnel costs increased by CHF 1.6 million through the addition of 16 FTEs with remaining increases of CHF 2.8 million in the area of consumables, depreciation of R&D equipment and regulatory and quality assurance
- **G&A Expenses:** For the year ended December 31, 2019, G&A increased CHF 3.6 million to CHF 16.1 million. Increases were driven by personnel and IT expenses
- **IFRS Income/(Loss) for the period:** The Company recorded net income after taxes of CHF 45.4 million for the year ended December 31, 2019, compared with net losses of CHF 50.9 million for 2018

2020 Financial Guidance
For the full year 2020, the Company expects its total cash burn to range between CHF 65–80 million at constant exchange rates.

About AC Immune SA
AC Immune SA is a Nasdaq-listed clinical-stage biopharmaceutical company, which aims to become a global leader in precision medicine for neurodegenerative diseases. The Company utilizes two proprietary platforms, SupraAntigen™ and Morphomer™, to design, discover and develop small molecule and biological therapeutics as well as diagnostic products intended to diagnose, prevent and modify neurodegenerative diseases caused by misfolding proteins. The Company's pipeline features nine therapeutic and three diagnostic product candidates, with six currently in clinical trials. It has collaborations with major pharmaceutical companies including Roche/Genentech, Lilly and Janssen.

For further information, please contact:

Head of Investor Relations
Joshua Drumm
AC Immune
Phone: +1 917 809 0814
Email: joshua.drumm@acimmune.com

US Media
Katie Gallagher
LaVoieHealthScience
Phone: +1 617 792 3937
Email: kgallagher@lavoiehealthscience.com

Global Head of Communications
Judith Moore
AC Immune
Phone: +41 79 826 63 82
Email: judith.moore@acimmune.com

European Investors & Media
Chris Maggos
LifeSci Advisors
Phone: +41 79 367 6254
Email: chris@lifesciadvisors.com

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. 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, 2019	As of December 31, 2018
ASSETS		
Non-current assets		
Property, plant and equipment	3,917	3,324
Right-of-use assets	2,255	—
Long-term financial assets	304	304
Total non-current assets	**6,476**	**3,628**
Current assets		
Prepaid expenses	2,788	2,364
Accrued income	1,095	3,667
Finance receivable	—	199
Other current receivables	304	236
Short-term financial assets	95,000	30,000
Cash and cash equivalents	193,587	156,462
Total current assets	**292,774**	**192,928**
Total assets	**299,250**	**196,556**
SHAREHOLDERS' EQUITY AND LIABILITIES		

Shareholders' equity		
Share capital	1,437	1,351
Share premium	346,526	298,149
Accumulated losses	(75,521)	(121,877)
Total shareholders' equity	**272,442**	**177,623**
Non-current liabilities		
Long-term financing obligation	—	186
Long-term lease liabilities	1,813	—
Net employee defined benefit liabilities	7,485	5,665
Total non-current liabilities	**9,298**	**5,851**
Current liabilities		
Trade and other payables	142	1,979
Accrued expenses	11,797	10,420
Short-term deferred income	4,477	351
Short-term financing obligation	652	332
Short-term lease liabilities	442	—
Total current liabilities	**17,510**	**13,082**
Total liabilities	**26,808**	**18,933**
Total shareholders' equity and liabilities	**299,250**	**196,556**

Statements of Income/(Loss)
(in CHF thousands except for per share data)

	For the years ended December 31,		
	2019	**2018**	**2017**
Revenue			
Contract revenue	111,026	7,194	20,255
Total revenue	**111,026**	**7,194**	**20,255**
Operating expenses			
Research & development expenses	(50,432)	(44,277)	(32,663)
General & administrative expenses	(16,058)	(12,467)	(10,131)
Total operating expenses	**(66,490)**	**(56,774)**	**(42,794)**
Operating income/(loss)	**44,536**	**(49,550)**	**(22,539)**
Finance income / (expense), net	(2,046)	(1,132)	(4,055)
Change in fair value of conversion feature	4,542	—	—
Interest income	304	29	330
Interest expense	(1,894)	(298)	(147)
Finance result, net	**906**	**(1,401)**	**(3,872)**
Income/(loss) before tax	**45,442**	**(50,951)**	**(26,411)**
Income tax expense	—	—	—
Income/(loss) for the period	**45,442**	**(50,951)**	**(26,411)**

Income/(loss) per share (EPS):			
Basic income/(loss) for the period attributable to equity holders	0.64	(0.82)	(0.46)
Diluted income/(loss) for the period attributable to equity holders	0.64	(0.82)	(0.46)

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

	For the years ended December 31,		
	2019	**2018**	**2017**
Income/(loss) for the period	45,442	(50,951)	(26,411)
Other comprehensive income/(loss) not to be reclassified to income or loss in subsequent periods (net of tax):			
Re-measurement losses on defined benefit plans (net of tax)	(1,304)	(302)	(780)
Total comprehensive income/(loss), net of tax	**44,138**	**(51,253)**	**(27,191)**

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)	**2019**	**2018**	**2017**
Income/(Loss)	**45,442**	**(50,951)**	**(26,411)**
Adjustments:			
Non-cash share-based payments (a)	2,834	2,518	1,579
Foreign currency (gains)/losses (b)	826	1,179	4,168
Effective interest expense (c)	1,355	—	—
Change in fair value of conversion feature (d)	(4,542)	—	—
Adjusted Income/(Loss)	**45,915**	**(47,254)**	**(20,664)**
Earnings/(Loss) per share – basic	0.64	(0.82)	(0.46)
Earnings/(Loss) per share – diluted	0.64	(0.82)	(0.46)
Adjustment to earnings/(loss) per share – basic	0.01	0.06	0.10
Adjustment to earnings/(loss) per share – diluted	0.00	0.06	0.10
Adjusted earnings/(loss) per share – basic	**0.65**	**(0.76)**	**(0.36)**
Adjusted earnings/(loss) per share – diluted	**0.64**	**(0.76)**	**(0.36)**
Weighted-average number of shares used to compute Adjusted Loss per share – basic	70,603,611	61,838,228	57,084,295
Weighted-average number of shares used to compute Adjusted Loss per share – diluted	71,103,341	61,838,228	57,084,295

a. 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.
b. Reflects foreign currency remeasurement gains and losses for the period, predominantly impacted by the change in the exchange rate between the US Dollar and the Swiss Franc.
c. Effective interest expense for the period relates to the accretion of the Company's convertible loan in accordance with the effective interest method.

d. 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, 2019, 2018 and 2017, were CHF 0.4 million in net gains, CHF 3.7 million in net losses and CHF 5.7 million in net losses, respectively. The Company recorded CHF 2.8 million, CHF 2.5 million and CHF 1.6 million for the years ended December 31, 2019, 2018 and 2017, respectively, for share-based compensation expenses. There were foreign currency remeasurement losses of CHF 0.8 million, CHF 1.2 million, CHF 4.2 million for the years ended December 31, 2019, 2018 and 2017, 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 and gains in 2018 nor 2017, respectively.



Source: AC Immune SA