# AC Immune Q3 2019 Financial Results and Business Update

November 13, 2019

***CHF 32 Million in Milestone Revenues***

***Multiple Upcoming Catalysts***

***Execution Across Clinical and Preclinical Neurodegenerative Development Pipeline***

LAUSANNE, Switzerland, Nov. 13, 2019 (GLOBE NEWSWIRE) -- AC Immune SA (NASDAQ: ACIU), a Swiss-based biopharmaceutical company with a broad clinical-stage pipeline focused on neurodegenerative diseases, today provided a business and clinical update and reported its consolidated financial results for the third quarter of 2019.

**Prof. Andrea Pfeifer, Ph.D., CEO of AC Immune, commented:** "AC Immune, together with our leading pharmaceutical partners, is advancing one of the industry's broadest, most diversified development pipelines targeting neurodegenerative diseases. This quarter, we continued to demonstrate strong progress across our pipeline of potentially best-in-class small molecule, antibody, and vaccine therapeutics, as well as our cutting-edge diagnostic agents. This resulted in milestones achieved totaling CHF 32 million which were comprised of CHF 30 million from Eli Lilly and Company and EUR 2 million (CHF 2.2 million) from Life Molecular Imaging."

Prof. Pfeifer continued, "We anticipate multiple catalysts in 2019 and 2020, highlighted by expected Phase 2 data for semorinemab, our anti-Tau antibody partnered with Genentech/Roche, which we anticipate will be the first Phase 2 data available for a Tau-targeted therapy in Alzheimer's disease (AD). We also anticipate achieving further progress across our development pipeline with both early and late stage data readouts that we believe will build substantial value for the Company."

AC Immune's unique, multi-pronged approach is designed to address the full spectrum of neurodegenerative diseases. By selectively targeting misfolded pathological proteins both intracellularly and extracellularly, and by creating state-of-the-art diagnostic imaging agents that enable early detection of multiple disease pathologies and tracking of disease progression, AC Immune is pioneering a personalized medicine approach to deliver the right therapy to the right patient at the right time.

**Research & Development Highlights**

- Earned a EUR 2 million (CHF 2.2 million) milestone following initiation of longitudinal Phase 2 clinical development of next-generation Tau positron emission tomography (PET) tracer PI-2620 by partner Life Molecular Imaging
- Received first CHF 30 million milestone payment from Lilly based on achievement of preclinical milestones related to the oral small molecule Tau Morphomer™ program, which is currently advancing in a Phase 1 clinical study. A second CHF 30 million milestone payment is scheduled for Q1 2020, linked to achievement of further development milestones
- Vaccinated the first patient in a Phase 1b/2a study of anti-phospho-Tau (anti-pTau) vaccine candidate ACI-35.030 in collaboration with Janssen Pharmaceuticals. ACI-35.030 is intended as a disease-modifying treatment for AD and other Tauopathies
- Recently hosted a key opinion leader (KOL) event focused on the therapeutic and diagnostic potential of targeting Tau pathology, which highlighted AC Immune's differentiated Tau pipeline candidates and key updates from the ACI-3024 Tau Morphomer™ small molecule and ACI-35.030 programs
- Awarded a new grant from The Michael J. Fox Foundation for the Company's pioneering alpha-synuclein (a-syn) PET tracer program. If successful, AC Immune's program could deliver the world's first imaging agent capable of accurately detecting and monitoring progression of Parkinson's disease

**Analysis of Financial Statements for the Three and Nine Months Ended September 30, 2019**

- **Cash Position**: The Company had a total cash balance of CHF 302.5 million, comprised of CHF 212.5 million in cash and cash equivalents and CHF 90.0 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 116 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 from December 31, 2018 to CHF 292.4 million from CHF 177.6 million. Further details are available in our corresponding Financial Statements filed on the accompanying Form 6-K

- **Revenues:** Revenues for the three and nine months ended September 30, 2019 totaled CHF 33.4 million and CHF 110 million, respectively. This represents an increase of CHF 31.1 million and CHF 104.2 million compared to the respective periods in 2018. The increase for the three-month period relates to the recognition of CHF 30.0 million for the first installment of the first milestone achieved with Lilly and EUR 2 million (CHF 2.2 million) in connection with the initiation of a Phase 2 Trial of Tau PET Tracer with Life Molecular Imaging. The increase for the nine-month period is driven by the recognition of CHF 74.6 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 installment of the first milestone achieved with Lilly

- **R&D Expenditures:** R&D expenditures decreased by CHF 0.1 million (-0.6%) and increased CHF 3.6 million (+11%) for the three and nine months ended September 30, 2019 compared to the comparable periods in 2018, respectively. The increase in R&D expenditures in 2019 was largely due to increased investments in non-AD and new discovery programs. For non-AD, the Company increased investment in its Morphomer™ alpha-synuclein programs and continued to advance the clinical development of its anti-Abeta vaccine ACI-24 in Down Syndrome (DS). In new discovery, the Company continued to focus on its neuroinflammation discovery programs while also increasing investment in its anti-a-synuclein antibody. For AD, the Company's expenditures for the anti-pTau vaccine program decreased due to the completion of certain toxicology and manufacturing work in the prior year as well as a decrease for ACI-24 related to higher costs for the initiation of the Phase 2 study in the prior period

- **G&A Expenses**: For the three and nine months ended September 30, 2019, G&A increased CHF 1.0 million (+35%) and CHF 2.1 million (+24%) to CHF 4.0 million and CHF 10.8 million, respectively. Increases are driven by rental, personnel and IT expenses

- **IFRS Income/(Loss) for the period:** The Company recorded net income after taxes of CHF 18.2 million and CHF 64.9 million for the three and nine months ended September 30, 2019, respectively, compared with net losses of CHF 13.5 million and CHF 36.3 million for the comparable periods in 2018

**About AC Immune**

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 is utilizing two proprietary discovery 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 five currently in clinical trials. It has collaborations with major pharmaceutical companies including Roche/Genentech, Lilly and Janssen Pharmaceuticals Inc.

As a strategic leader in the field of neurodegenerative diseases, AC Immune has developed a five-point *Roadmap to Successful Therapies for Neurodegenerative Diseases* that recognizes the importance of treating earlier, targeting Tau, focusing on more homogeneous patient populations, precision medicine and exploring neuroinflammation as a target.

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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. 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**

| | As of September 30, 2019 | As of December 31, 2018 |
|---|---|---|

in CHF thousands

**ASSETS**

| | | |
|---|---|---|
| **Non-current assets** | | |
| Property, plant and equipment | 3,702 | 3,324 |
| Right-of-use assets | 1,893 | - |
| Long-term financial assets | 304 | 304 |
| **Total non-current assets** | **5,899** | **3,628** |
| | | |
| **Current assets** | | |
| Prepaid expenses | 2,997 | 2,364 |
| Accrued income | 939 | 3,667 |
| Finance receivable | 100 | 199 |
| Other current receivables | 2,957 | 236 |
| Short-term financial assets | 90,000 | 30,000 |
| Cash and cash equivalents | 212,457 | 156,462 |
| **Total current assets** | **309,450** | **192,928** |
| **Total assets** | **315,349** | **196,556** |
| | | |
| **SHAREHOLDERS' EQUITY AND LIABILITIES** | | |
| | | |
| **Shareholders' equity** | | |
| Share capital | 1,436 | 1,351 |
| Share premium | 346,479 | 298,149 |
| Accumulated losses | (55,532) | (121,877) |
| **Total shareholders' equity** | **292,383** | **177,623** |
| | | |
| **Non-current liabilities** | | |
| Long-term financing obligation | 297 | 186 |
| Long-term lease liabilities | 1,467 | - |
| Long-term deferred income | 1,092 | - |
| Net employee defined benefit liabilities | 6,098 | 5,665 |
| **Total non-current liabilities** | **8,954** | **5,851** |
| | | |
| **Current liabilities** | | |
| Trade and other payables | - | 1,979 |
| Accrued expenses | 8,551 | 10,420 |
| Short-term deferred income | 4,701 | 351 |
| Short-term debt obligation | 334 | 332 |
| Short-term lease liabilities | 426 | - |
| **Total current liabilities** | **14,012** | **13,082** |
| **Total liabilities** | **22,966** | **18,933** |
| **Total shareholders' equity and liabilities** | **315,349** | **196,556** |

**Statements of Income/(Loss)**

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |

| | (in CHF thousands except for per share data) | | | |
|---|---|---|---|---|
| **Revenue** | | | | |
| Contract revenue | 33,411 | 2,305 | 109,964 | 5,791 |
| **Total revenue**. | **33,411** | **2,305** | **109,964** | **5,791** |
| | | | | |
| **Operating expenses** | | | | |
| Research & development expenses | (11,478) | (11,546) | (35,770) | (32,150) |
| General & administrative expenses | (3,956) | (2,930) | (10,835) | (8,703) |
| **Total operating expenses** | **(15,434)** | **(14,476)** | **(46,605)** | **(40,853)** |
| **Operating income/(loss)** | **17,977** | **(12,171)** | **63,359** | **(35,062)** |
| | | | | |
| Finance income / (expense), net | 249 | (1,314) | (1,564) | (1,149) |
| Change in fair value of conversion feature | — | — | 4,542 | — |
| Interest income | 73 | — | 237 | 3 |
| Interest expense | (86) | (31) | (1,686) | (66) |
| **Finance result, net** | **236** | **(1,345)** | **1,529** | **(1,212)** |
| **Income/(loss) before tax** | **18,213** | **(13,516)** | **64,888** | **(36,274)** |
| **Income tax expense** | — | — | — | — |
| **Income/(loss) for the period** | **18,213** | **(13,516)** | **64,888** | **(36,274)** |
| | | | | |
| Income/(loss) per share (EPS): | | | | |
| Basic income/(loss) for the period attributable to equity holders | 0.25 | (0.21) | 0.92 | (0.61) |
| Diluted income/(loss) for the period attributable to equity holders | 0.25 | (0.21) | 0.92 | (0.61) |

**Statements of Comprehensive Income/(Loss)**

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |
| | (in CHF thousands) | | | |
| Income/(loss) for the period | 18,213 | (13,516) | 64,888 | (36,274) |
| 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 | — | — | — | — |
| Total comprehensive income/(loss), net of tax | 18,213 | (13,516) | 64,888 | (36,274) |

**Reconciliation of Income/(Loss) to Adjusted Income/(Loss) and Earnings/(Loss) Per Share to Adjusted Earnings/(Loss) Per Share**

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |
| | (in CHF thousands except for share and per share data) | | | |
| **Income/(Loss)** | **18,213** | **(13,516)** | **64,888** | **(36,274)** |
| **Adjustments:** | | | | |
| Non-cash share-based payments (a) | 882 | 583 | 2,027 | 1,897 |
| Foreign currency (gains)/losses (b) | (272) | 1,296 | 286 | 1,101 |

| | | | | |
|---|---|---|---|---|
| Effective interest expense (c) | — | — | 1,355 | — |
| Change in fair value of conversion feature (d) | — | — | (4,542) | — |
| **Adjusted Income/(Loss)** | **18,823** | **(11,637)** | **64,014** | **(33,276)** |
| | | | | |
| **Earnings/(Loss) per share – basic** | 0.25 | (0.21) | 0.92 | (0.61) |
| **Earnings/(Loss) per share – diluted** | 0.25 | (0.21) | 0.92 | (0.61) |
| **Adjustment to earnings/(loss) per share – basic** | 0.01 | 0.03 | (0.02) | 0.05 |
| **Adjustment to earnings/(loss) per share – diluted** | 0.01 | 0.03 | (0.01) | 0.05 |
| **Adjusted earnings/(loss) per share – basic** | **0.26** | **(0.18)** | **0.91** | **(0.56)** |
| **Adjusted earnings/(loss) per share – diluted** | **0.26** | **(0.18)** | **0.91** | **(0.56)** |
| Weighted-average number of shares used to compute Adjusted earnings/(loss) per share – basic | 71,822,884 | 64,862,822 | 70,184,257 | 59,912,283 |
| Weighted-average number of shares used to compute Adjusted earnings/(loss) per share – diluted. | 72,281,264 | 64,862,822 | 70,700,690 | 59,912,283 |

(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.

For the three and nine months ended September 30, 2019, adjustments increased net income and decreased net income by CHF 0.6 million and CHF 0.9 million compared with decreases to the net losses by CHF 1.9 million and CHF 3.0 million for the comparable periods in 2018, respectively. The Company recorded CHF 0.9 million and CHF 2.0 million for the three and nine months, respectively, for share-based compensation expenses. There were foreign currency remeasurement gains of CHF 0.3 million and remeasurement losses of CHF 0.3 million, respectively, related to foreign currency fluctuations. The Company recorded nil and CHF 1.4 million for amortization of effective interest for the three and nine months ended September 30, 2019, respectively. Finally, the Company recognized nil and a CHF 4.5 million gain for the change in fair value of the liability related to the conversion feature.

Source: AC Immune SA