AC Immune's Alzheimer's Disease Vaccine-candidate ACI-35.030 Selected for Further Development

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- Data presented at CTAD 2022 confirm excellent clinical performance of ACI-35.030 vaccine candidate
- Based on this new clinical data, ACI-35.030 has been selected for further development representing significant progress for the anti-pTau vaccine candidate
- AC Immune vaccine portfolio targeting three hallmark proteins of neurodegenerative diseases now progressing through advanced clinical development

Lausanne, Switzerland, November 30, 2022 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today announced that based on the Phase 1b/2a interim data, ACI-35.030, a potential first-in-class anti-phosphorylated-Tau (pTau) vaccine candidate, has been selected for further development. The ACI-35.030 anti-pTau vaccine candidate is being developed in collaboration with Janssen Pharmaceuticals, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Dr. Andrea Pfeifer, CEO of AC Immune SA, commented: "The selection of ACI-35.030 for further development is a significant step for this collaboration. Early clinical testing showed that ACI-35.030 was generally well tolerated and induced specific activity against the pathological species of Tau, including the neurotoxic pTau and enriched paired helical filaments (ePHF) species, both of which are closely implicated in Alzheimer's disease (AD). The excellent performance of ACI-35.030 in the trial participants (average age approximately 65 years) potentially opens promising avenues for AD treatment and prevention, which could offer an important societal impact. We thank the team at Janssen for their contributions of valuable knowledge, expertise, and resources to support this collaboration."

The selection of ACI-35.030 is supported by new clinical data from the Phase 1b/2a trial presented at the Clinical Trials on Alzheimer's Disease (CTAD) Conference 2022. The results show that ACI-35.030 treatment rapidly leads to the strong and durable induction of antibodies specific for pathological forms of Tau such as pTau and its aggregated form, ePHF. The ACI-35.030-induced antibody response was sustained and could be periodically boosted over a period of 72 weeks. The vaccine candidate was generally well tolerated. The decision to select ACI-35.030 follows the comparison, presented at CTAD, demonstrating its strengths relative to a protein conjugate vaccine, JACI-35.054, an alternative anti-pTau vaccine also being evaluated in parallel in the Phase 1b/2 trial.

Dr. Andrea Pfeifer, CEO of AC Immune SA, added: "Looking forward into 2023 AC Immune will have three vaccine candidates in Phase 2 development, highlighting the Company's position as a leader in active vaccination for neurodegenerative diseases. Importantly, our vaccine programs are complemented by additional therapeutic and diagnostic candidates driving our precision medicine approach in neurodegenerative diseases. Some programs have already generated significant revenues from collaborations with companies such as Janssen, Eli Lilly, Genentech (Roche), and Life Molecular Imaging. Collectively, these programs form the most comprehensive pipeline in neurodegenerative disease, with clinical candidates targeting Tau, Abeta, and alpha-synuclein. We look forward to advancing these programs towards additional value creating milestones as our pipeline matures and grows."

About the SupraAntigen® platform

AC Immune's clinically validated SupraAntigen ® platform uses proprietary liposomes to rapidly generate novel vaccines (SupraAntigen®-V) for active immunization as well as best-in-class monoclonal antibodies (SupraAntigen®-A) for passive immunization against key neurodegenerative disease targets. Products generated by the platform are highly specific for the pathological conformations of misfolded proteins and are well tolerated. The SupraAntigen® platform has successfully generated multiple vaccine and antibody candidates that have been validated in clinical studies and has led to multiple global partnerships with world-leading pharmaceutical companies. In addition to targeting amyloid-beta and Tau, AC Immune has generated conformation-specific antibodies against emerging neurodegenerative disease targets including alpha-synuclein, TDP-43 and the NLRP3-ASC inflammasome pathway.

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 ten therapeutic and three diagnostic candidates, six of which are currently in phase 2 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 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 and SG. 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. 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.

Attachment

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Source: AC Immune SA